

105 CMR: DEPARTMENT OF PUBLIC HEALTH  
Approved by the Public Health Council on September 24, 2008  
The following does not constitute the official version of the regulations

105 CMR 164.000 Licensure of Substance Abuse Treatment Programs

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**LICENSURE OF SUBSTANCE ABUSE TREATMENT PROGRAMS**

**PART ONE: APPLICABLE TO ALL LICENSEES**

**164.001 Purpose and Effective Date**

105 CMR 164.000 sets forth standards for the licensure and operation of all substance abuse treatment programs in Massachusetts. The effective date of 105 CMR 164.001-164.454 is December 26, 2008.

**164.002 Authority**

105 CMR 164.000 is adopted under the authority of M.G.L. c. 111B, §§ 6, 6A and 6B, c. 111E, § 7 and c. 90, §§ 24, 24D and 24P.

**164.003 Citation**

105 CMR 164.000 shall be known, and may be cited, as 105 CMR 164.000: Licensure of Substance Abuse Treatment Programs.

**164.004 Scope**

105 CMR 164.000 shall govern the licensure or approval and operation of every substance abuse treatment program subject to licensure or approval under M.G.L. c 111B, §§ 6, 6A; c 111E § 7; c 90 §§ 24 and 24D. A department, agency or institution of the federal government, the Commonwealth or any political subdivision thereof is exempt from licensure except that a department, agency or institution of the Commonwealth or subdivision thereof is subject to approval by the Department. No person, corporation, trust, authority, governmental agency, political subdivision or any other entity subject to these regulations shall operate a substance abuse treatment program or treatment services that do not comply with the requirements of 105 CMR 164.000. The Department may from time to time publish interpretations of 105 CMR 164.000 and guidelines as necessary to promote uniform application of 105 CMR 164.000, and make them available to those licensed and approved by the Department and to the public.

**164.005 Severability**

Any section, subsection, paragraph, sentence, clause, phrase, or word of 105 CMR 164.000 declared to be invalid for any reason shall be severed and shall not affect any other portion of 105 CMR 164.000, which shall remain in full force and effect.

**164.006 Definitions**

The following definitions shall apply to these regulations, unless an alternative interpretation is specifically provided:

**Acupuncture Detoxification and Maintenance Program** - a treatment program providing acupuncture services for individuals experiencing the dysfunctional effects of the use of alcohol and/or other drugs, whose primary need is detoxification to manage withdrawal symptoms, and thereafter, support services for maintenance of sobriety.



**Acupuncturist** - an individual licensed by the Board of Registration in Medicine in accordance with M.G.L. c. 112, §§ 150 through 156.

**Administrator** - the Executive Director, Program Director or other individual responsible for the day-to-day operations of a facility or program.

**Adolescent** - a child age 13 through 17 inclusive.

**Advertisement** - in accordance with Consumer Protection regulations 940 CMR 6.000 Retail Advertising (including the terms "advertise" and "advertising"), any oral, written, graphic, or pictorial representation made by a licensee in the course of the solicitation of consumers of services or which encourages a person to utilize services. Advertisement includes any representation made in any media including digital or electronic media, newspaper, magazine, or other publication or on radio or television or contained in any notice, handbill, sign, billboard, banner, poster, display, circular, pamphlet, catalog, or letter, or printed on or contained in any tag or label, which is attached to or accompanies any product offered for sale. Advertisement includes any representation disseminated within Massachusetts if the advertisement is directed to consumers in Massachusetts.

**Agency** - a legal entity to which one or more license(s) or approval(s) is granted by the Department for the delivery of the service.

**American Psychiatric Association** - a professional organization of psychiatrists which defines and codifies psychiatric conditions for purposes of diagnosis.

**American Society of Addiction Medicine**- also, ASAM - a medical society of physicians engaged in addiction treatment, education, research and program improvement.

**Applicant** - anyone requesting a license or approval from the Department to operate the program or service.

**Approval** - a certification, in writing, whether full or provisional, issued by the Department to a private or public entity or institution, which authorizes it to operate a program subject to 105 CMR 164.000.

**Audit** - a professional independent review, examination and verification of financial and accounting records and supporting documents by a professional, such as a Certified Public Accountant, to verify their accuracy and render an opinion as to their fairness, consistency, and conformity with Generally Accepted Accounting Principles (GAAP) and to recommend necessary changes in controls, policies, or procedures.

**Board of Directors** - the governing body of a corporation usually made up of officers of the corporation and outside (non-company) directors.

**Building** - also, Premises - the physical structure in which services are provided.

**Bureau** - the Bureau of Substance Abuse Services of the Department of Public Health, including its staff.

**Business Day** - a day on which the offices of the Commonwealth are open for regular business.

**Case Aide**- also Orderly or Unit Assistant - an individual responsible for daily management within a 24 hour structured residential program.

**Case Manager** - an individual responsible for assisting clients to obtain needed services by providing information, referral coordination and follow-up.

**Case Record** - a unified, comprehensive collection of documentation concerning a client in a substance abuse treatment program.

**Chain of Custody** - a process of monitoring possession of samples, such as saliva, urine or blood, to prevent tampering with the sample or the results. Chain of custody begins with collection of the sample, and continues through final reporting of test results.

**Child** - any person under 18 years of age.

**Client** - also Patient or Resident - a person applying for admission or admitted to a program, facility or agency providing substance abuse services.

**Clinical Supervision** - a regular and specified time set aside to provide training, education and guidance to direct care staff and to oversee the provision of client services. Supervision may be provided on an individual or group basis, provided that groups do not exceed eight individuals.

**Clinician** - an individual with a minimum of (1) a master's degree in one of the following disciplines or a closely related field: clinical psychology, education-counseling, medicine, psychology, psychiatric nursing, rehabilitative counseling, social work, and who has a minimum of one year of supervised substance abuse counseling experience; or (2) a bachelor's degree in any of the listed disciplines and either a minimum of three years of supervised substance abuse counseling experience, or has a recognized certification or licensure including 4,000 hours of clinically supervised counseling of individuals with substance use disorders including at least 220 documented hours of supervision.

**Commissioner** - Commissioner of Public Health.

**Commonwealth** - every executive office, department, board, commission, division or authority of the Massachusetts state government or political sub-division of any of the foregoing.

**Community Served** - the population defined by substance abuse treatment need and other characteristics such as gender, language, age or residence, to whom a licensee provides substance abuse treatment services.

**Continuum of Care** - a principle of substance abuse treatment that includes a range of substance abuse treatment services based on six dimensions established by the American Society of Addiction Medicine: alcohol intoxication/withdrawal potential; biomedical conditions and complications; emotional/behavioral conditions and complications; treatment acceptance/resistance; relapse continued use potential; and recovery environment.

**Consultation** - the presentation of specific patient cases to clinicians of equal or greater expertise for the purpose of feedback, direction and guidance.

**Co-occurring Disorders** - diagnosis of both a substance use disorder and one or more mental health disorders in one individual.

**Counselor** - an individual who has a minimum of a high school diploma or equivalent and a minimum of one year supervised counseling experience in substance abuse treatment or a closely related field.

**Day Treatment Program** - a treatment program licensed by the Department that provides direct client services through group, individual, and family substance abuse counseling a minimum of five days per week.

**Department** - the Department of Public Health.

**Division of Health Care Quality** - also DHCQ - the division of the Department of Public Health whose responsibilities include licensing and inspecting hospitals and clinics.

**Direct Care Staff** – personnel who provide direct individual, group, educational, clinical or case management services to clients of substance abuse treatment programs.

**Disability** – a physical or mental impairment that substantially limits one or more of the major life activities of an individual; a record of such an impairment; or being regarded as having such an impairment (28 CFR Section 35.104).

**Driver Alcohol Education (DAE) Program** - an educational program licensed by the Department and established for individuals adjudicated by a court as first offenders of laws prohibiting driving under the influence of intoxicating liquor or controlled substances.

**Executive Director** - the individual duly appointed by the governing body of the agency, who is responsible for the day-to-day operations of the agency providing substance abuse treatment services.

**Facility** – a substance abuse intervention or treatment agency that is publicly or privately owned, for-profit or not-for-profit.

**Family Therapist** – an individual licensed by the Massachusetts Board of Registration of Allied Mental Health Professions in accordance with M.G.L. c. 112, § 165.

**Food service personnel** – staff who prepare and serve meals, oversee food storage, and are responsible for sanitary care of food preparation and serving equipment.

**Full-time equivalent (FTE)** - a minimum of 35 hours per week per each staff position.

**Inpatient Detoxification Service** – a residential program of substance abuse evaluation and withdrawal symptom care provided in freestanding or hospital-based settings.

**Levels of Care** - the range of substance abuse treatment services based on patient placement criteria defined by the American Society of Addiction Medicine.

**License** - authorization, in writing, issued by the Department upon its determination that the applicant is a responsible and suitable agency to operate a substance abuse treatment program under the authority granted to the Department by M.G.L. c. 111B, §§ 6, 6A and 6B; c. 111E, § 7; c. 90 §§ 24 and 24D.

**Licensee** - any person holding a license or approval from the Department to operate a substance abuse treatment program. In the case of a licensee which is not a natural person, the term licensee shall also mean any shareholder owning 5% or more of the outstanding stock; any limited partner owning 5% or more of the partnership interests and any general partner of a partnership licensee; any trustee of any trust licensee; any sole proprietor of any licensee which is a sole proprietorship; any mortgagee in possession; and any executor or administrator of any licensee which is an estate.

**Licensed Practical Nurse** - an individual licensed by Massachusetts Board of Registration in Nursing in accordance with M.G.L. c. 112, § 74A.

**Medical Director** - a physician licensed to practice medicine in the Commonwealth of Massachusetts, with specialized training in addiction medicine, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific

responsibility to authorized program physicians and qualified healthcare professionals functioning under the medical director's direct supervision.

**Medical Clearance** - determination by physician, nurse practitioner, physician assistant, registered nurse, or a licensed practical nurse duly licensed/certified in the Commonwealth of Massachusetts that an individual shows no signs or symptoms of withdrawal requiring medical monitoring or management.

**Medically Supervised Withdrawal** - dispensing of an opioid medication in gradually decreasing doses to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of opioid drugs. The purpose of medically supervised withdrawal is to bring a patient maintained on maintenance medication to a medication-free state within a target period.

**Medication Unit** - a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer opioid agonist treatment or collect samples for drug testing or analysis.

**Mental and Behavioral Disorders Due to Psychoactive Substance Use** - the variety of disorders defined by the World Health Organization which are attributable to the use of one or more psychoactive and/or addictive substances.

**Need** - a demand for services exceeding availability of services.

**Nurse Practitioner** - an individual licensed by the Massachusetts Board of Registration in Nursing in accordance with M.G.L. c. 112, § 80B.

**Opioid Treatment** - dispensing of an opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological or physical effects incident to opiate addiction. This term encompasses detoxification treatment and maintenance treatment.

**Opioid Treatment Program** - SAMHSA-certified program, usually comprised of a facility, staff, administration, patients, and services, that engages in supervised assessment and treatment, using approved medications, of individuals who are addicted to opioids.

**Outpatient Counseling Program** - a program of substance abuse treatment services provided in an ambulatory setting for adults and adolescents, and their families, experiencing the dysfunctional effects of the use of alcohol or other drugs.

**Outpatient Detoxification Program** - a program of ambulatory substance abuse treatment that provides clinical management of withdrawal symptoms through medical, counseling, and ancillary treatment.

**Part One** - the first portion of these regulations, 105 CMR 164, from section 164.000 through section 164.087, containing requirements for applicants and licensees providing or seeking to provide any substance abuse treatment regardless of level of care.

**Part Two** - the second portion of these regulations, 105 CMR 164 from section 164.100 through 164.454, containing requirements for applicants and licensees providing or seeking to provide substance abuse treatment services for specific levels of care.

**Patient** - also Client or Resident - a person applying for admission or admitted to a program, facility or agency providing substance abuse services.

**Parent** - father or mother, guardian, or person or agency legally authorized to act on behalf of the child in place of, or in conjunction with, the father, mother, or guardian.

**Pharmacist** - an individual registered by the Massachusetts Board of Registration in Pharmacy in accordance with M.G.L. c. 112, § 24.

**Physician** - an individual licensed by the Massachusetts Board of Registration in Medicine in accordance with M.G.L. c. 112, § 2 .

**Physician Assistant** - an individual who is registered by the Board of Registration of Physician Assistants in accordance with M.G.L. c. 112, § 9I.

**Primary Facility** - the main premises of a facility licensed to provide substance abuse treatment services.

**Program** - an organized system of services containing a mission, philosophy and model of treatment designed to address the needs of clients.

**Program Director** - the individual employed by the licensee who is responsible for the day-to-day operations of a program of substance abuse treatment services.

**Program Sponsor** - the person responsible for the operation of an opioid treatment program.

**Provisional License** - a license or approval granted by the Department to an applicant for a period not to exceed six months, in accordance with provisions of 105 CMR 164.014 Provisional License.

**Psychiatrist** - a physician licensed by the Massachusetts Board of Registration in Medicine and certified by the American Board of Psychiatry and Neurology or an equivalent body.

**Psychologist** - an individual licensed by the Massachusetts Board of Registration of Psychologists in accordance with M.G.L. c. 112, §§ 118 through 121.

**Qualified Health Care Professional** - a Physician, Registered Nurse, Nurse Practitioner, Physician's Assistant or Licensed Practical Nurse trained to do physical assessments, and duly licensed, certified or registered as such in the Commonwealth of Massachusetts.

**Qualified Service Organization** - an individual, partnership, corporation, federal, state or local government agency, or any other legal entity, which: (a) provides services to a licensee and (b) has entered into a written agreement with the licensee.

**Qualified Service Organization Agreement** - a signed and dated document describing the agreed upon terms of a service relationship between the licensee and the qualified service organization, which meets the requirements of 42 CFR Part 2.

**Recovery Home** - a residential rehabilitation program that conforms to American Society of Addiction Medicine criteria for Medium-Intensity Residential Services.

**Recovery Specialist** - A staff person in a residential rehabilitation program who provides guidance and direction to residents, and oversees resident activities to ensure conformance with program policies. Recovery specialists who meet qualifications defined for Counselors may provide individual or group counseling services.

**Registered Nurse** - an individual licensed by the Massachusetts Board of Registration in Nursing in accordance with M.G.L. c. 112, § 74.

**Residential Rehabilitation** - a licensed facility that provides a therapeutic, planned regimen of substance abuse treatment and education services for persons in the early stages of recovery from addiction who require safe and stable living environments in order to develop recovery skills. Services are provided in a 24 hour live-in setting, with 24 hour per day staffing.

**Satellite Office** - an office operating at a site physically separate from the main premises of a facility licensed to provide outpatient substance abuse treatment services. A satellite office must be open to clients at least 20 hours per week and must offer a minimum of 40 staff hours a week of substance abuse treatment services.

**Second Offender Aftercare** - an educational and treatment program of a licensed outpatient facility for individuals who have been convicted of a second Driving While Under the Influence offense and who have completed, or are awaiting placement in, a 14 day Driving Under the Influence (DUI) second offender residential program.

**Senior Clinician** - an individual who has a master's degree in one of the following disciplines or a closely related field: clinical psychology, education-counseling, medicine, psychology, psychiatric nursing, rehabilitative counseling, social work; and two years of supervised substance abuse counseling experience; and at least one year full time equivalent year of clinical experience in a supervisory role.

**Social Model Recovery Home** - a Residential Rehabilitation program that conforms to the ASAM criteria for Low Intensity Residential Services.

**State Authority** - the Department of Public Health, designated by the Governor or other appropriate state official designated by the Governor, to exercise the responsibility and authority within the Commonwealth for governing the treatment of opiate addiction with an opioid drug.

**State Methadone Authority** - personnel of the Bureau authorized to approve requests for exceptions to limitations on take-home doses of methadone, and to review hearing decisions to terminate a client from an opioid treatment program.

**Substance Abuse Treatment License for Department of Mental Health Licensed Facility** - authorization, in writing, issued by the Department upon its determination that a mental health facility licensed by the Department of Mental Health (DMH) under M.G.L. c. 19, §19, meets applicable requirements of 105 CMR 164.000 to ensure the safety and adequacy of the substance abuse treatment program.

**Substance Use Disorder** - the range of conditions associated with alcohol, tobacco and other drug use, including substance dependence, abuse and withdrawal as defined by the American Psychiatric Association.

**Therapeutic Community** - a Residential Rehabilitation program that conforms to ASAM criteria for High-Intensity Residential Services.

**Tobacco Free** - an environment free of tobacco use including the use of smokeless tobacco, such as snuff and chewing tobacco.

**Training** - educational programs, workshops and other structured opportunities for staff aimed at improving skill, knowledge and service provision.

**Transfer of Ownership** - shall include but not be limited to the following:

- (1) a transfer of a majority interest in the ownership of the substance abuse treatment program;
- (2) in the case of a for profit corporation, transfer of a majority of any class of the stock thereof;
- (3) in the case of a partnership, transfer of a majority of the partnership interest;
- (4) in the case of a trust, change of the trustee or a majority of trustees;
- (5) in the case of a not-for profit corporation, such changes in the corporate membership and/or trustees as the Department determines to constitute a shift in control of the service; or
- (6) where foreclosure proceedings have been instituted by a mortgagee in possession.

Transitional Support Service – a short-term Residential Rehabilitation program.

**Viral Hepatitis** – for purposes of these regulations, viral hepatitis refers to Hepatitis B and Hepatitis C.

World Health Organization – an agency of the United Nations which directs and coordinates UN authority on international public health, and which compiles classifications of diseases and disorders.

Written Notice – (1) a letter sent by registered or certified mail; or (2) a written statement, receipt of which is documented by dated signature of both the individual sending and the individual receiving the notice. The period of time stated in the written notice shall be calculated beginning on the first business day following receipt of written notice.

**Licensing Procedures and Requirements**

**164.007 Applications Required**

- (A) Application for a license, approval, substance abuse treatment license for a Department of Mental Health licensed facility [hereinafter reference to license shall include substance abuse treatment license for a Department of Mental Health licensed facility where referenced in 164.012(D)(3)], or for renewal of a license or approval shall be filed on forms provided by the Department and accompanied by all supporting documents required by 105 CMR 164.000.
- (B) No entity, except a general hospital or clinic licensed by the Department, or a department, agency or institution of the federal government or of the Commonwealth, or any subdivision of those listed above, shall operate a substance abuse treatment program without a substance abuse treatment license from the Department.
- (C) No entity or program shall advertise or hold itself out as a substance abuse treatment program, or shall provide or require substance abuse treatment as part of its program requirements, without a license or approval from the Department, except as provided for in 105 CMR 164.012 (D).
- (D) Services established and provided by a department, agency, or institution of the Commonwealth shall file an application for approval for the establishment or provision of the service. Such services shall meet all requirements established for licensure under 105 CMR 164.000.
- (E) Hospitals or clinics described in 105 CMR 164.012 (D) shall apply for required licenses and approvals and must also meet those requirements established for licensure or approval under 105 CMR 164.012(D).

**164.008 Application Submission**

- (A) Applicants for an initial or renewal license or approval shall submit an application to the Department on an approved form obtained from the Department, in a manner prescribed by the Department, together with any other documents and materials that the Department deems appropriate.
- (B) All applications must be on Department forms, completed in full, and sworn to before a notary.
- (C) Fees shall accompany each application and shall be as follows:
  - (1) for each license application, excluding satellite offices and medication units, \$300;
  - (2) for each satellite office or medication unit, an additional \$75.00.
  - (3) Licensees seeking to add a service, satellite office or medication unit to an existing license shall submit documentation as required by the Department and an application fee of \$75 for each service, satellite office or medication unit.

Application fees are not refundable. No fee shall be required when the applicant is the Commonwealth.

**164.009 Access for Individuals with Disabilities**



**Applicants for license or approval shall complete the Department's checklist for ADA/504 compliance prior to submitting an application for licensure. The self-evaluation is subject to inspection as part of the licensing process.**

**164.010 Evaluation of Application and Suitability of Applicant or Licensee**

- (A) Upon receipt of a complete application or reapplication for licensure or approval the Department shall evaluate the suitability of the applicant or licensee including but not limited to the following factors. A negative determination with respect to any one of the factors constitutes an adequate ground for deeming an applicant or licensee unsuitable to establish or maintain a substance abuse treatment program and upon which the Department may deny an initial or renewal application for a license or approval.
- (1) Past performance as a provider of substance abuse treatment services, based upon documentation of applicant's or licensee's:
    - (a) history of compliance with these regulations;
    - (b) history of providing substance abuse treatment services or other health care services, including provision of services in other states;
    - (c) ability to provide substance abuse treatment services;
    - (d) history of response to correction orders issued under 105 CMR 164.016;
    - (e) history of failure to provide services to any individual when licensed or approved to provide such services; and
    - (f) history of client abuse, mistreatment or neglect in any licensed health care program or facility.
  - (2) Whether the applicant's or licensee's financial resources are sufficient to provide substance abuse treatment services for which the applicant seeks a license.
  - (3) Whether the licensee or applicant is in compliance with all laws of the Commonwealth relating to taxes and child support and whether the applicant has workers compensation and professional and commercial insurance coverage.
  - (4) The record of compliance for health care facilities in the Commonwealth or other jurisdictions, including any limitation on, suspension or revocation of, or refusal to grant or renew a health care license or certification for Medicaid or Medicare to the applicant or licensee.
  - (5) The adequacy of the applicant's or licensee's legal capacity to operate, as demonstrated by such documents as articles of incorporation and corporate by-laws.
  - (6) Any attempt to obtain a license or approval by fraud, misrepresentation, or the submission of false information.
  - (7) Capacity to meet the requirements for licensing or approval as a substance abuse treatment program.
  - (8) Such other information as the Department may require.
- (B) If the Department is unable to make a finding of suitability due to the existence of any of the factors listed in 164.010 (A) (1)-(8), the applicant or licensee shall have the burden of persuasion to prove the applicant's or licensee's suitability.

**164.011 Inspections**

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- (A) The Department or its agents may visit at any time without prior notice and inspect the facility, its staff, activities, and records to determine compliance with 105 CMR 164.000 and applicable state and federal laws. Such visits shall be conducted:
  - (1) prior to the granting or renewing of a license or approval;
  - (2) for the purpose of on-going monitoring and evaluating the licensee, and for the purpose of assuring compliance with these regulations; and
  - (3) during investigation of a complaint.
- (B) Applicants and licensees shall provide Department inspectors with access to:
  - (1) the entire physical plant, including those portions open to clients and staff and those open only to staff;
  - (2) records, and documentation related to the provision of substance abuse treatment services, and to the operation of the program or agency, including personnel records and documents relating to the licensed legal entity. All such records and documentation shall be in English, legible, and current to within five business days of the most recent provision of service.
- (C) Refusal to allow entry to Department inspectors shall constitute grounds to seek a warrant in district or superior court to authorize entry.
- (D) Refusal to allow entry to the Department inspectors shall constitute adequate and independent grounds for denial, suspension, revocation, and/or refusal to grant or renew a license or approval.

164.012 License

- (A) The Department shall not approve an application for an initial or renewal license or approval unless there is need for the service and it determines the applicant's suitability to establish or maintain the service in accordance with 105 CMR 164.010.
- (B) Upon satisfactory submission of an application and completion of an inspection(s), the Department may grant a license, approval, or renewal for a term of six months or two years.
- (C) No one shall operate any substance abuse treatment program without a current license, approval or "substance abuse treatment license for a Department of Mental Health licensed facility" as required under 105 CMR 164.000. Whoever knowingly operates such a program or services without obtaining a license, approval, or "substance abuse treatment license for a Department of Mental Health licensed facility" may be subject to penalties up to a fine of \$500.00 for the first offense and up to \$1,000.00 for each subsequent offense or by imprisonment for not more than two years or both.
- (D) Licensing requirements for substance abuse treatment programs in hospitals and clinics.
  - (1) No free-standing substance abuse treatment facility shall operate unless it:
    - (a) meets the requirements of 105 CMR 164.000 and is licensed by the Department under M.G.L. c. 111B, § 6 and M.G.L. c. 111E, § 7; and
    - (b) meets all applicable regulatory requirements for medical care standards established by 105 CMR 130.000.
  - (2) No general hospital licensed by the Department of Public Health under M.G.L. c. 111, § 51, shall provide, hold itself out as providing or advertise that it provides a separate, identifiable inpatient or outpatient substance abuse treatment program unless it:
    - (a) meets all applicable requirements under 105 CMR 130.000; and

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- (b) meets all applicable requirements for substance abuse treatment under 105 CMR 164.000 as set forth in Appendix A and is approved to provide substance abuse treatment by the Department;
    - (c) except that any outpatient SAMHSA accredited opioid treatment program must meet the full requirements of 105 CMR 164.000.
  - (3) No free-standing mental health facility licensed by the Department of Mental Health under M.G.L. c. 19, § 19, shall provide, hold itself out as providing or advertise that it provides a separate, identifiable inpatient substance abuse treatment program unless it:
    - (a) has a current and valid Department of Mental Health license; and
    - (b) meets all applicable requirements for substance abuse treatment under 105 CMR 164.000 as set forth in Appendix B, and the Department grants it a “substance abuse treatment license for a Department of Mental Health licensed facility”.
  - (4) No free-standing mental health facility licensed by the Department of Mental Health as an inpatient psychiatric facility or inpatient psychiatric unit of a general hospital licensed by the Department of Mental Health pursuant to M.G.L. c. 19, § 19, shall provide any inpatient medically monitored detoxification or opioid treatment unless it:
    - (a) develops and follows inpatient medically monitored detoxification or opioid treatment protocols. Such protocols shall be submitted to the Bureau for approval as part of the Department of Mental Health licensure process; and
    - (b) refrains from providing, advertising or holding itself out as providing a separate identifiable substance abuse treatment program.
  - (5) A clinic licensed by the Department under 105 CMR 140.000 that provides treatment for substance abuse disorders, as defined in 105 CMR 140.020(7) must meet all applicable regulatory requirements for substance abuse treatment services established by 105 CMR 164.000.
- (E) No license or approval may be transferred or assigned to any other service, program, agency, entity or location.
- (F) Transfer of ownership:
- (1) Suitability: At least 90 calendar days in advance of any transfer of ownership, any applicant who intends to acquire a substance abuse treatment program shall submit a Notice of Intent to the Department on a form supplied by it. The Department shall notify each applicant in writing of the date on which the form is deemed completed. Within 90 days of such date, the Department shall complete its suitability review for licensure pursuant to the standards of 105 CMR 164.010. With the consent of the applicant, the Department may extend the 90 day suitability determination period for a maximum of 30 days.
  - (2) Circumvention: A transfer of ownership shall not be recognized and the new owner shall not be considered suitable for licensure when the transfer is proposed or made to circumvent the effect and purpose of 105 CMR 164.000. The Department shall consider the following factors in determining whether a transfer has been proposed or made to circumvent the regulations:
    - (a) the transferor's record of compliance with Department licensure laws and regulations;
    - (b) the transferor's current licensure status;
    - (c) the transferor's familial, business or financial relation to the transferee;
    - (d) the terms of the transfer.
  - (3) Application for Licensure: A person applying for a license or approval as a result of any transfer of ownership, after a finding by the Department of suitability pursuant to 105 CMR

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**164.012 (F) (1) shall file an application for licensure within 48 hours of the transfer unless an extension of the 48 hour period is granted by the Department.**

- (4) A license or approval application filed as a result of a transfer of ownership, if timely filed as required by 105 CMR 164.012 (F) (3), shall have the effect of a license or approval from the date of transfer until such time as the Department takes action on the application. If not timely filed, an application will not have such effect and the license shall lapse.
- (5) Any notice of hearing, order, or decision which the Department or Commissioner issues to a facility prior to a transfer of ownership shall be effective against the former owner prior to transfer and, where appropriate, the new owner following the transfer unless the notice, order, or decision is modified or dismissed by the Department or the Commissioner.
- (G) An applicant for a change in location shall be subject to all requirements of initial licensure. Licensees shall request prior written authorization of the Department for each site proposed for the delivery of services and for any change in location of an existing service.
- (H) An applicant for a change in name shall be required only to notify the Department pursuant to 105 CMR 164.035 (A) and to submit all relevant or requested documents, provided that there is no change in ownership, location or control of the facility.

**164.013       Renewal of License**

- (A) Applicants seeking renewal of a license or approval shall meet all requirements for licensure or approval specified in 105 CMR 164.000, except as provided for in 105 CMR 164.012(D)(2)(b) and (3)(b).
- (B) Applicants for renewal must submit to the Department completed forms and fees required by the Department at least 60 days prior to the expiration of the current license or approval.
- (C) If the complete renewal application is timely filed with the Department, the license or approval shall not expire until the Department makes a determination on the renewal application.
- (D) If an application is not submitted timely, the service may not continue to operate after the expiration of its license or approval without the written permission of the Department.

**164.014       Provisional Licenses**

- (A) The Department may issue a provisional license or approval in response to a new application for an applicant not previously licensed.
- (B) When the Department finds that an applicant for renewal of licensure has not complied with all applicable regulations, but is in substantial compliance and has submitted an acceptable plan of correction for bringing the facility into full compliance, the Department may issue a provisional license, provided that:
  - (1) The applicant demonstrates to the Department's satisfaction a good faith intent to meet all the requirements;
  - (2) The Department finds that the service offered protects the health and safety of the facility's clients; and
  - (3) The Department finds that the applicant evidences the potential for full compliance within a reasonable period of time, not to exceed six months.

- (C) A provisional license or approval is valid for a period not to exceed six months and may be renewed once for no more than six months. The Department may issue a provisional license or approval only when an applicant submits a written plan for full compliance. This written plan shall include specific target dates for achieving full compliance.

**164.015 Posting of License**

Each licensee shall post the current license or approval issued by the Department in a conspicuous public place at each service location.

**164.016 Correction Orders**

After every inspection in which any violation of 105 CMR 164.000 is observed, the Department shall prepare a written deficiency correction order citing every violation observed, a copy of which shall be sent to the licensee. The deficiency correction order shall include a statement of the deficiencies found, the period within which the deficiency must be corrected, and the provision(s) of law and regulation relied upon.

**164.017 Plan of Correction**

- (A) The licensee shall submit to the Department a written plan for correction of each violation cited in a deficiency correction order within a time period specified by the Department in the correction order.
- (B) The plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for each step, and the date by which full compliance will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible. The plan of correction shall be signed by either the applicant or licensee or his/her designee.
- (C) Unless the Department states in the deficiency correction order that more urgent corrective action is necessary, based on the seriousness of the deficiency, the licensee shall be given a maximum 30 days from receipt of the correction order to remove the deficiency. The Department may specify a different date by which the correction(s) shall be completed, in the event that the licensee requests additional time and the Department determines that it is necessary.
- (D) The Department shall review the plan of correction and will notify the licensee of either the acceptance or rejection of the plan. An unacceptable plan must be amended and resubmitted within ten business days of the date of notice of rejection.
- (E) Failure to submit an acceptable and timely plan of correction or failure to timely correct in accordance with the plan are grounds for an enforcement action including suspension or revocation of a license.

**164.018 Grounds for Suspension of License**

The Commissioner may summarily suspend a license or approval if the continued operation of the program or service poses an immediate threat to the health or safety of its clients. The licensee may not operate during the period of suspension of its license, after notification of the suspension.

**164.019 Grounds for Denial, Refusal to Renew, Restriction, Limitation, or Revocation of License**

Each of the following, in and of itself, shall constitute full and adequate grounds to deny, revoke, limit, restrict, or refuse renewal of a license or approval:

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- (A) Failure to satisfy the Department as to any of the grounds for determining suitability of the application under 105 CMR 164.010.
- (B) Failure to meet the applicable requirements for licensure as specified in 105 CMR 164.000 *et seq.*
- (C) Failure to meet the requirements of applicable federal or state law or regulations.
- (D) Failure to comply with the laws of the Commonwealth related to taxes, child support, and workers' compensation, or failure to maintain professional and commercial insurance coverage.
- (E) Violation of any applicable requirement of 105 CMR 164.000.
- (F) Failure to give proper care to clients.
- (G) Failure to submit an acceptable plan of correction pursuant to 105 CMR 164.017.
- (H) Failure to remedy or correct a cited violation.
- (I) Denial of entry to agents of the Department or attempt to impede the work of a duly authorized representative of the Department.
- (J) Knowingly making an omission of material information or providing false or misleading statements orally or in writing to the Department.
- (K) The applicant or licensee operated the facility without a required license or approval or after the expiration of a license or approval if the applicant or licensee has not timely submitted an application for renewal.
- (L) There is a reasonable basis for the Department to conclude that there is a discrepancy between the representations by a facility as to the treatment services to be afforded patients and the treatment services actually rendered or to be rendered.
- (M) Conviction of an applicant or licensee or a person with significant financial or management interest in the service of Medicare or Medicaid fraud or other criminal offense related to the operation of the service.
- (N) Conviction of an applicant or licensee or a person with significant financial or management interest in the program of a violent crime against a person, which indicates that operation of the service may endanger the public health or safety.
- (O) Other grounds: Nothing herein shall limit the Department's adoption of policies and grounds for denial, refusal to renew, or revocation through adjudication, as well as through rule making.

**164.020**      **Hearings**

**(A) Denial of an Initial Application for Licensure or Approval**

- (1) If the Department denies an initial application for licensure or approval pursuant to 105 CMR 164.020 (A)(1), the Department shall notify the applicant in writing of the following:
  - (a) the intended action;
  - (b) the reason(s) and ground(s) for the action; and
  - (c) the applicant's or licensee's right to file a written request for an adjudicatory hearing in accordance with M.G.L. c. 30A and the Standard Adjudicatory Rules and Practice and Procedure, 801 CMR 1.01 *et seq.*

- (2) The applicant may request a hearing on the Department's decision. A written request for a hearing shall be submitted within 14 business days of receipt of the notice. Upon receipt of an applicant's request for a hearing, the Department shall provide an opportunity for a hearing as described in 105 CMR 164.020 (C) if:
  - (a) the Department determines that sufficient material facts exist;
  - (b) the applicant has sufficiently specified those material factual matters in dispute.
- (3) When an application is denied based on facts over which there is no material dispute, the applicant shall be notified in writing of the reasons for denial, and shall not be entitled to an adjudicatory hearing but may seek judicial review under M.G.L. c. 30A, §14.

**(B) Suspension of a License or Approval**

- (1) Upon suspension of a license or approval, or any part thereof, the Commissioner shall give the licensee notice thereof, stating the reason(s) and grounds for the suspension. The suspension shall take effect immediately upon issuance of the notice.
- (2) Upon written request made within 14 days of receipt of the written notice, the licensee shall be promptly afforded a hearing pursuant to 801 CMR 1.00.
- (3) The hearing officer shall determine whether the Department has proved by a preponderance of the evidence that there existed immediately prior to, or at the time of suspension, an immediate threat to the health and safety of the clients or staff.

**(C) Restriction, Limitation, Revocation, or Refusal to Renew a License or Approval**

- (1) If the Department determines that a license or approval should be restricted, revoked, or refused renewal, it shall provide written notice to the applicant or licensee of:
  - (a) the intended action;
  - (b) the reason(s) and ground(s) for the action; and
  - (c) the applicant's or licensee's right to file a written request for an adjudicatory hearing in accordance with M.G.L. c. 30A and the Standard Adjudicatory Rules and Practice and Procedure, 801 CMR 1.01 *et seq.* The written request must be submitted within 14 business days of receipt of the Department's written notice.
- (2) Upon receipt of Notice of Claim for an Adjudicatory Proceeding made within 14 days of receipt of the Department's written notice, the Department shall initiate a hearing pursuant to 801 CMR 1.01 *et seq.*
- (3) The hearing officer shall determine whether the Department has proved by a preponderance of evidence that the license or approval should be denied, restricted, limited, revoked, or refused renewal based upon relevant facts as they existed at or prior to the time that the Department initiated the action.
- (4) If the hearing officer finds any single ground for denial, restriction, limitation, revocation, suspension, or refusal to renew a license, the hearing officer shall render a recommended decision affirming the decision of the Department.

**164.021 Commissioner and Judicial Review**

- (A) The Commissioner shall review the recommended decision of the hearing officer in any adjudicatory proceeding conducted pursuant to 801 CMR 1.01 *et seq.* The decision of the

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Commissioner shall constitute a final agency decision in an adjudicatory proceeding, and is subject to judicial review pursuant to M.G.L. c. 30A, § 14.

- (B) A licensee or applicant that fails to exercise the right to an adjudicatory proceeding pursuant to 105 CMR 164.020 waives both the right to administrative review by the Commissioner and the right to judicial review pursuant to M.G.L. c. 30A, § 14.

**164.022 Provision of Information to the Department**

- (A) Each licensee shall timely submit management information data in a form required by the Department including, but not limited to, admissions, discharges, client characteristics, services and outcomes, and staff patterns and characteristics. It shall also submit to the Department such data, statistics, schedules, or information as the Department may require for the purposes of licensing and/or monitoring and evaluating a service as well as data required to meet federal reporting requirements including, but not limited to, outcome data.
- (B) Each licensee is responsible for requesting client authorizations, if deemed necessary, to ensure the timely submission of data to the Department.
- (C) All information submitted pursuant to the requirements of 105 CMR 164.000 or otherwise required by the Department shall be kept current by each licensee.
- (D) A licensee who fails to furnish such data, statistics, schedules or information as the Department requires, or who files fraudulent information, shall be punished by a fine pursuant to M.G.L. c. 111B, § 6B or M.G.L. c. 111E, § 7, and shall be subject to revocation of its license or approval under 105 CMR 164.019.

**164.023 Waivers**

- (A) A service, program or facility may request a waiver of one or more of the requirements imposed by 105 CMR 164.000, by submitting a written request for such a waiver which supports the reason(s) for the request.
- (B) The Department may, in its discretion, waive the applicability of one or more of the requirements of 105 CMR 164.000, upon a written finding that:
  - (1) compliance would cause undue hardship to the facility; the licensee shall document such hardship in a manner defined by the Department;
  - (2) the facility is in substantial compliance with the spirit of the requirement and has instituted compensating features that are acceptable to the Department;
  - (3) the facility's non-compliance does not jeopardize the health or safety of its clients and does not limit the facility's capacity to provide the service; and
  - (4) the facility provides to the Department written documentation supporting its request for a waiver.
- (C) The Department may, in its discretion, rescind or impose a time limit on any waiver it grants.

**Licensee Administration and Organization**

**164.030 Governance**

- (A) The licensee shall have a governing body that is accountable for and has authority over the policies and activities of the service and which includes persons with expertise in management, finances



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- (1) Records of the governing body shall specify the number of its members who are expert in each category listed above and who are in recovery from a substance use disorder. Such records need not identify these members by name.
  - (2) If the governing body is unable to recruit and retain members who are in recovery from a substance use disorder, it shall
    - (a) document efforts made to recruit and retain such members;
    - (b) establish a local advisory board of persons in recovery, and obtain at least annually from this board a review of agency services and programs;
    - (c) review the comments of the advisory board as described in subsection 164.030 (A) (2) (b) above; and
    - (d) document efforts under (b) and (c) above.
  - (3) If the agency's governing body is located outside of Massachusetts, the governing body shall establish an advisory board in Massachusetts comprised of Massachusetts residents from the community served, and shall include at least one person in recovery from a substance use disorder.
- (B) The duties and responsibilities of the governing body shall include:
- (1) appointment of an executive director;
  - (2) establishment of an employment contract with an executive director;
  - (3) orientation for board members;
  - (4) annual conflict of interest disclosures by board members;
  - (5) oversight of programs, goals, budgets, operational reviews and licensure status;
  - (6) establishment of staggered term limits;
  - (7) definition of decision-making process;
  - (8) definition of scope of responsibilities for board and executive director;
  - (9) establishment of standing committees, at least one of which shall be on audit and finance;
  - (10) maintaining records documenting actions taken in accordance with (B) (1) through (9) above, and records of:
    - (a) minutes and records of meetings;
    - (b) reports to the governing body by the executive director;
    - (c) instructions and guidance provided to the executive director by the governing body;
    - (d) reviews by the governing body of the executive director's performance, which shall be conducted at least annually; and
    - (e) the governing body's review and approval of the licensee's audit and annual operating budget.
- (C) The licensee shall submit the following information to the Department:
- (1) the names, addresses and phone numbers of all owners, officers, directors, and financial investors whether they are individuals, general and/or limited partnerships, corporate bodies, or subdivisions of other bodies, and anyone else that meets the definition of licensee; the licensee shall notify the Department of any changes to this information at the same time the licensee notifies the Massachusetts Secretary of State; and
  - (2) ownership or financial interest in the service, program or agency held by current employees, including the nature of such interest and the financial benefits received by the employee. The disclosure shall also state if no benefits are received.
- (D) The licensee shall maintain, and make available to any employee or client an organizational chart and written policy that describe the organizational structure including lines of authority, responsibility, communication, and staff assignment.

- (E) The licensee shall appoint a program director who shall administer the day-to-day operations of the facility and who shall be on the premises during regular business hours. In his/her absence a professional staff person shall be designated to act in his/her place. The licensee shall provide the designee with contact information for the administration in the event of an emergency.
- (F) Each licensee shall establish a system of business management and staffing to ensure that the facility maintains complete and accurate audits, accounts, books, and records, including required financial, personnel, and client records.
- (G) All records required by 164.030 (A) through (F) shall be made available for review during inspection visits conducted in accordance with 105 CMR 164.011 Inspections.

**164.031 Accreditation**

Licensees who are subject to accreditation by any state, federal or national organization shall obtain and maintain their accreditation and shall provide documentation of the accreditation to Department.

**164.032 Finances**

- (A) The applicant or licensee shall demonstrate financial capability to operate the facility for the licensing period. The licensee shall annually, on or before the 15<sup>th</sup> day of the fifth month after the end of its fiscal year, document a complete audit, including a management letter. This report shall be provided to the Department in a manner specified by the Department.
- (B) The licensee shall keep and maintain an accurate record of the finances of the facility in accordance with state requirements and its by-laws.
- (C) The licensee shall keep on file an annual operating budget with documentation of approval by its governing body. The budget shall categorize revenues by source of funds and expenses by service components and shall include a variance report.
- (D) The licensee shall establish written policies and procedures for all fiscal operations, including fee arrangements with clients. In the event of client non-payment, prior to moving to discharge the client, the licensee shall:
  - (1) make reasonable efforts to secure payment from a third-party payment source; and
  - (2) offer a reasonable payment plan which takes into account the client's income and resources.

**164.033 Insurance**

- (A) Each licensee shall have general and professional liability insurance.
- (B) Each licensee shall have acceptable evidence of compliance with the workers' compensation insurance coverage required by M.G. L. c. 152, § 25C.

**164.034 Qualified Service Organization Agreements**

When qualified service organizations provide services, programs, agencies or facilities to the licensee, the licensee shall establish written agreements with these organizations. The qualified service organization agreements shall:

- (A) be signed by both parties,
- (B) be renewed at least every two years, and

- (C) require the qualified service organization to agree to be bound by requirements of 42 CFR Part 2 governing the confidentiality of information regarding clients receiving substance abuse services.

**164.035 Required Notifications to the Department**

- (A) Change of Name, Ownership, or Location: at least 90 days prior to a change in location, name, ownership or control of the facility, the licensee shall notify the Department in writing of the proposed change, and shall comply with applicable provisions of 105 CMR 164.012 (F) through (H)
- (B) Legal Proceedings: The licensee shall report in writing to the Department any civil action or criminal charge that is brought against the licensee or any person employed by the licensee that relates to the delivery of the service or may affect the continued operation of the facility. The report shall be given to the Department as soon as the licensee is aware of the action and no later than 24 hours of the initiation of any legal action or within 24 hours of service of notice upon the licensee or its agent, whichever occurs first.
- (C) Closure: When a licensee plans to cease operation the licensee shall:
- (1) notify the Department in writing at least 90 days prior to cessation of operations and closure. Such notification shall specify the date of closure and shall include the licensee's plan for closure as required by 164.087 Closure. Voluntary closure shall include foreclosure or bankruptcy proceedings.
  - (2) In the case of involuntary closure not due to an action of the Department, notify the Department as soon as the licensee is aware of the pending closure and prior to cessation of operations and closure.
- (D) Interruption or Suspension of Service: If a licensee determines that the health, safety or well-being of clients is in imminent danger as a result of conditions existing within the service, program or facility, the licensee shall notify the Department immediately upon becoming aware of the danger to clients. The Department shall consult with the licensee regarding the need to interrupt or suspend services as provided for in 164.086 Interruption or Suspension of Services.
- (E) Change of Program or Service Provision: A licensee shall notify the Department in writing at least 30 days before any change in program or service provision. The Department shall determine whether such change requires re-licensure.
- (F) Change of Administrator, Executive or Program Director: A licensee shall notify the Department at least two weeks before a planned change of Administrator, Executive or Program Director. In the event of an unplanned departure of a director, the licensee shall notify the Department within two (2) business days of the change of director.
- (G) Death, Serious Incident, Accident or Fire:
- (1) The licensee shall notify the Department in writing within one business day of learning of the death of any person currently admitted to the program, regardless of where the death occurs. Where appropriate, the licensee shall notify the decedent's family or next-of-kin.
  - (2) The licensee shall orally notify the Department immediately, and in writing within one business day of any serious injury which occurs under program auspices, regardless of location.
  - (3) The licensee shall orally notify the Department immediately, and in writing within one business day of any fire or other event resulting in damage to the program.

(H) **Safety and Health Conditions:** The licensee shall orally notify the Department immediately, and in writing within one business day, of the following:

- (1) any alleged abuse or neglect, or physical or sexual assault, which occurs between or among clients at the program, or which occurs between or among clients and staff regardless of location, including any incident which is reported to another agency or law enforcement.
- (2) any condition at the program which poses a threat to the health or safety of clients or staff, for example, conditions which limit access, unsanitary conditions, fire hazards, loss of essential services, regardless of whether the conditions cause an interruption of service. The licensee shall consult with the Department to determine whether the condition requires an interruption or suspension of service, as provided for in 164.086 Interruption or Suspension of Service.
- (3) confirmed cases among staff or clients of communicable diseases which are reportable under 105 CMR 300 Reportable Diseases.

(I) **Reports of Abuse and Neglect:** When alleged abuse or neglect occurs at the program, the licensee shall immediately notify the Department of:

- (1) any reports of child abuse or neglect made under M.G.L. c. 119, §. 51A;
- (2) any reports of elder abuse or neglect made under M.G.L. c. 19A, § 15; and
- (3) any reports of abuse of a disabled person made under M.G.L. c. 19C.

#### 164.036 Marketing of Services

A licensee may advertise for clients by means that are in the public interest. Advertising that is not in the public interest includes advertising which:

- (1) is false, deceptive or misleading;
- (2) has the effect of intimidating or exerting undue pressure;
- (3) guarantees a cure; and/or
- (4) makes claims of professional superiority which a licensee cannot substantiate.

#### 164.037 Goals and Objectives

Each licensee shall adopt and maintain a current written statement of purpose identifying service goals, objectives, and philosophy. The licensee shall review this statement annually and modify it as necessary, reflecting changes in the characteristics of the clients served, changes within the community where the service is located, or recommended changes as a result of a facility evaluation. This statement shall also be maintained in the client policy manual as outlined in 105 CMR 164.081 Client Policy Manual.

#### 164.038 Evaluation

The licensee shall implement an evaluation plan that enables it to measure progress toward the achievement of its established goals and objectives. The evaluation plan shall be prepared annually by the licensee and reviewed with the governing body. The plan shall address methods for reviewing appropriateness of client care, utilization of service components, methods for achieving compliance with the federal and state disability laws, and other data and information necessary for analyzing and improving the efficiency and effectiveness of program services. The licensee shall designate the individual(s) responsible for completing the evaluation plan, and shall document the application of the evaluation findings to its efforts to improve program services.

#### 164.039 Non-Discrimination and Accommodation

The licensee shall ensure that all aspects of agency and program operation comply with requirements of the Americans with Disabilities Act and with Section 504 of the Rehabilitation Act of 1973, and with

**Section 104 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, by establishing policies and procedures providing that:**

- (A) No qualified person with a disability shall, on the basis of such disability, be excluded from participation in, be denied equal benefit of, or otherwise be subjected to discrimination under any program, service, activity or employment opportunity.
- (B) Programs and services are accessible to individuals with disabilities, including accommodation to ensure that communication with persons with disabilities is as effective as it is for other program participants.
- (C) If the licensee is a faith-based organization, the licensee shall not require clients to participate in religious practices.

**164.040      Written Policies**

- (A) Each licensee shall have written policies and procedures consistent with and implemented in accordance with the requirements established in 105 CMR 164.000, Department administrative guidelines, accepted standards of care for substance abuse treatment services and applicable laws. All policies required under 105 CMR 164.000 shall be in writing, and available to staff, clients and Department inspectors, and shall at a minimum address:
  - (1) organizational structure including lines of authority, responsibility, communication, personnel practices, and staff assignment;
  - (2) statement of goals and objectives of the program;
  - (3) types of services offered;
  - (4) fiscal management including establishment and collection of fees;
  - (5) admission, termination and discharge, including involuntary termination, aftercare, post-discharge and follow-up;
  - (6) program rules;
  - (7) confidentiality;
  - (8) security of and access to client records and client information;
  - (9) personnel including policy governing sexual harassment;
  - (10) non-discrimination and accommodation;
  - (11) when providing inpatient and residential services: care of client possessions, safe storage, administration and disposal of medication, handling of client mail, visits and communication;
  - (12) transfer or referral of a client to another program or for additional services not provided directly by licensee;
  - (13) behavior management;
  - (14) grievances;
  - (15) staff response to client threats to harm self or others;
  - (16) submission of mandated reports of child abuse or neglect under M.G.L. c. 119, § 51A, elder abuse under M.G.L. c. 19A, § 15, and abuse of a disabled person under M.G.L. c. 19C, § 4 and maintenance of records of any such reports made by staff;
  - (17) responses to and reports of death, accident, injury, fire and alleged assault, and responses to and reports of safety and health conditions at the program; and
  - (18) all-hazard and emergency planning and procedures;
  - (19) employee assistance;
  - (20) orientation and supervision of staff from contract or temporary agencies; and
  - (21) for licensees providing opioid treatment services, severe weather.
- (B) Standards for the content of required policies may be set by administrative requirements issued from time to time by the Department.

**164.041 Personnel**

- (A) 105 CMR 164.041 through 164.046 apply to all staff, including volunteers and interns.
- (B) The licensee shall comply with requirements of federal Equal Employment Opportunity Laws and with M.G.L. c. 151B, § 4 prohibiting discrimination in employment and M.G.L. c. 151B, § 3A governing employers' policies regarding sexual harassment.
- (C) A licensee who serves a community in which a majority of the population do not speak English as a first language shall make and document efforts to employ staff in direct service positions who speak the language(s) of the community served.
- (D) The licensee shall ensure that all employees are screened annually for Tuberculosis (TB).
- (E) The licensee shall comply with the hiring restrictions established by the Executive Office of Health and Human Services under 101 CMR 15.00: Criminal Offender Record Checks.

**164.042 Personnel Policies**

- (A) Each licensee shall describe in writing the facility's current personnel policies and practices and shall make them available to all staff members.
- (B) Such personnel policies shall include a description of:
  - (1) the criteria and procedures for hiring, assigning, promoting, and suspending or dismissing a staff member;
  - (2) the procedure for handling staff complaints and grievances;
  - (3) prohibition of sexual harassment and procedures for handling sexual harassment complaints;
  - (4) prohibited interactions between staff and clients;
  - (5) provisions for vacations, holidays, paternity and maternity leave, educational leave, sick leave, other leaves of absence, and fringe benefits;
  - (6) staff member accident and safety procedures;
  - (7) employee assistance plan;
  - (8) restrictions on the use of tobacco products and smoking ; and
  - (9) requirements of 42 CFR Part 2 (federal confidentiality regulations) and 45 CFR Parts 160, 162 and 164 (Health Insurance Portability and Accountability Act, HIPAA), where applicable.

**164.043 Job Description and Evaluations**

- (A) The licensee shall make available job descriptions for all positions, which shall include current salary ranges. Job descriptions shall specify responsibilities, supervision received, supervision provided to others, degree of authority to execute job responsibilities, and qualifications.
- (B) The licensee shall evaluate the job performance of all staff members. Each evaluation shall be completed at least annually, and a copy shall be placed in the employee's personnel record.
- (C) The licensee shall include the following job descriptions, which may be incorporated into descriptions for other positions:
  - (1) Access Coordinator: responsible for development and implementation of the licensee's ADA/504 self-evaluation and annual updates;
  - (2) HIV/AIDS Coordinator: responsible for overseeing confidential HIV risk assessment and access to counseling and testing; staff and client HIV/AIDS and hepatitis education; and Department requirements for admission, service planning and discharge of HIV positive clients;

- (3) **Tobacco Education Coordinator:** responsible for assisting staff in implementing BSAS guidelines for integration of tobacco assessment, education and treatment into program services.

**164.044 Training and Supervision**

- (A) The licensee shall provide ongoing staff training and supervision appropriate to the size and nature of the facility and staff involved. The licensee shall have a written plan for supervision which shall specify the frequency and goals of supervision for all staff, and which shall provide that all direct care staff receive clinical supervision, and that supervision is documented. At a minimum, the licensee shall establish the following supervision requirements:
- (1) Staff who provide clinical services and staff who are engaged in direct care of clients shall receive a minimum of one hour of individual or group supervision every other week from a staff person of greater experience and training.
  - (2) Staff who are engaged in direct care of clients and who are not full-time employees of the service shall receive supervision in proportion to the number of hours worked.
- (B) The licensee shall have a written plan for the professional growth and development of all personnel. The plan shall include the following:
- (1) orientation and ongoing supervision of employees regarding policies and procedures of the agency, including program operations; state and federal confidentiality laws; professional ethics; behavioral management; record keeping; internal incident reporting and investigation; and the reporting of abuse and neglect of children, the elderly and disabled persons; and
  - (2) over the course of a year, monthly scheduled in-service training sessions on, at a minimum,
    - (a) agency's or program's All Hazards Emergency Response Plan;
    - (b) HIV/AIDS, sexually transmitted diseases (STDs) and Viral Hepatitis ;
    - (c) universal health precautions and infection control;
    - (d) substance use disorders including tobacco and nicotine addiction, clinical assessment and diagnosis; treatment planning; relapse prevention and aftercare planning;
    - (e) co-occurring disorders, including mental health disorders, gambling and other addictive behaviors;
    - (f) other topics specific to the requirements of the level of care and/or the population served.
- (C) The licensee shall provide specific training for the Access, HIV/AIDS and Tobacco Education Coordinators.
- (D) The licensee shall utilize a training model for HIV/AIDS that develops staff skills to provide direct client education in either an individual or group setting, and which encompasses related illnesses such as Hepatitis and sexually transmitted diseases. Such a model shall include at least:
- (1) the etiology and transmission of HIV infection, Viral Hepatitis, STDs and associated risk behaviors;
  - (2) symptomatology and clinical progression of HIV infection and AIDS;
  - (3) prevention of transmission, or risk reduction for HIV, Viral Hepatitis and STDs;
  - (4) the purpose, uses, and meaning of available testing and test results;
  - (5) confidentiality requirements; and
  - (6) the interaction between alcohol and other drug use and its effect on the immune system and the progression of HIV/AIDS.
- (E) Program Directors, Clinical Directors or staff designated as Tobacco Education Coordinators shall complete the tobacco treatment basic skills training as specified by the Department.

- (F) The licensee shall maintain a record of all in-service training sessions provided, including topic, date, duration and attendance.

**164.045 Employee Assistance**

The licensee shall have a written policy and procedure for assisting employees, which shall include the following provided directly or through qualified service organization agreements:

- (A) Confidential assessment and referral for services related to personal or professional difficulties which affect the employee's ability to perform assigned duties, including substance use disorders, gambling or other addictive behaviors, and domestic violence.
- (B) Response for employees who experience injury or stress related to workplace incidents.
- (C) Information about tobacco treatment programs, and encouragement of staff to utilize resources.

**164.046 Personnel Records**

- (A) The licensee shall maintain a personnel record for each employee.
- (B) Such records shall be kept confidentially and at a minimum include:
- (1) a copy of the employee's application for employment or resume;
  - (2) documentation of the employee's current certification, license, or registration, where applicable laws and/or regulations require certification, licensure, or registration;
  - (3) evidence of training received, as specified in 105 CMR 164.044 (B) Training and Supervision;
  - (4) if trained in cardiopulmonary resuscitation (CPR), documentation of current certification;
  - (5) documentation of an annual TB screening, including recommendations and follow-up;
  - (6) annual performance evaluations; and
  - (7) documentation of employee training regarding confidentiality requirements of 42 CFR Part 2, and, if required, 45 CFR Parts 160 and 164.
- (C) Results of Criminal Offender Records Checks shall be maintained in separate files.

**164.047 Volunteers, Student Interns and Contract Agency Staff**

- (A) Volunteers and student interns may be used only as an adjunct to regular paid staff and not as a substitute for a paid work force. Student interns and volunteers providing individual and/or group counseling shall be screened, oriented, trained, and supervised in a manner consistent with 105 CMR 164.044 Training and Supervision and 105 CMR 164.041 (E).
- (B) When a licensee uses staff who are employed by a contract or temporary agency, the licensee shall ensure the following:
- (1) the licensee has established a qualified service organization agreement with the contract or temporary agency which specifies that the contract or temporary agency has complied with hiring restrictions established by the Executive Office of Health and Human Services under 101 CMR 15.00: Criminal Offender Record Checks.
  - (2) the licensee has established a written policy and procedure to ensure such staff receive orientation and supervision, and to document such orientation and supervision.

**164.048 Staffing Pattern**



- (A) The licensee shall provide an adequate number of qualified personnel to fulfill the service objectives.
- (B) The licensee shall establish a multidisciplinary team that includes professionals with recognized expertise in a variety of areas of substance abuse treatment. The team may include licensee's staff as well as other treatment professionals through Qualified Service Organization Agreements. The team may include physicians, psychiatrists, psychologists, acupuncturists, nurse practitioners, physician assistants, registered nurses, licensed practical nurses, social workers, psychiatric nurses, substance abuse counselors with master's or bachelor's degrees in a related field and certified or licensed substance abuse counselors.
- (1) The multidisciplinary team shall review initial assessments, treatment plans and other client-specific issues to ensure quality of services and to provide education and training to staff.
- (2) The licensee shall ensure that the multidisciplinary team is incorporated into the staffing plan.
- (C) In addition, the licensee shall ensure that on each shift specific staff members are designated to:
- (1) Initiate an emergency response as described in section 105 CMR 164.062 All Hazards Emergency Planning and Procedures; and
- (2) Perform cardio-pulmonary resuscitation.
- (D) The licensee shall establish a staffing pattern which includes paid staff in numbers, qualifications and shift coverage to ensure:
- (1) provision of required services
- (2) safety of clients and staff
- (3) operation of the program in accordance with 105 CMR 164.000.

The Department may issue guidance specifying minimum numbers of staff, and may determine that a staffing pattern is insufficient to ensure 105 CMR 164.048 (D) (1) through (3).

**164.049 Physical Plant: Building Design**

- (A) The design, construction, and furnishings of the building shall comply with all federal and state laws and local ordinances pursuant to 105 CMR 164.050 Required Inspections.
- (B) All sites where services are delivered shall be fully accessible to individuals with disabilities in accordance with the Department's Access for Individuals with Disability Policy.
- (C) Each site shall have sufficient and appropriate space for storage of client records. Confidential client records shall be kept at the licensed premises under lock and key and secured so that only authorized agency staff has access to them. Closed client records may be stored off-site under lock and key and secured so that only authorized personnel have access to them.

**164.050 Required Inspections**

- (A) The licensee shall identify the local, town, city or state authority or authorities responsible for conducting building, fire and sanitary code inspections, in accordance with M.G.L. c. 143 Inspection and Regulation of Buildings, etc., and M.G.L. c. 148 Fire Prevention. Such determinations shall be in writing, including written statements of exemptions.
- (B) The licensee shall ensure that all required inspections identified under 164.050 (A) are current, and documented in writing.

- (C) Documentation required under (A) and (B) above shall be made available to the Department's inspector.

**164.051 Heating**

- (A) Each building shall be equipped with a heating system that is sufficient to maintain a minimum temperature of 68°F throughout the building during cold weather. Portable heaters are prohibited.
- (B) The heating system shall comply with the rules and regulations as outlined by the Department of Public Safety (522 CMR – Board of Boiler Rules, and 527 CMR – Board of Fire Protection Regulations) under M.G.L. c. 148.
- (C) Plumbing and heating shall be adequate to maintain a comfortable and healthy environment for clients. Hot water supplied to fixtures accessible to clients shall be regulated to ensure a minimum temperature of 110°F and a maximum temperature of 130°F.

**164.052 Lighting**

Adequate electric lighting, maintained in good repair, shall be provided at the recommended levels of the Illumination Engineering Society throughout the building and in exterior areas. All electrical installations shall be in accordance with the Board of Fire Prevention Regulations (527 CMR), Massachusetts Electrical Code (527 CMR 12.00), and all local regulations.

**164.053 Building Maintenance**

- (A) All licensees shall provide sufficient maintenance and housekeeping personnel to insure that the building is in good repair and in a safe, clean, and sanitary condition and free from accumulation of refuse. Residential rehabilitation programs may require residents to maintain sleeping quarters in clean and safe condition and to perform light housekeeping tasks. Residential rehabilitation programs shall not require residents to serve as substitutes for maintenance and housekeeping personnel.
- (B) Each building shall have adequate space for storage of equipment and bulk office supplies and all storage areas, attics, and cellars shall be kept safe and free from accumulations of refuse. Combustibles, whose storage is permissible under relevant state and local regulations, shall be kept in metal cabinets.
- (C) All doorways, corridors, and stairwells shall be well-lighted and maintained so as to provide free and unobstructed egress from all parts of the building:
- (1) an emergency source of lighting shall be available in all corridors and stairways that lead to the principal means of egress;
  - (2) all stairways shall be equipped with handrails; and
  - (3) areas around the buildings, sidewalks, and patios shall be kept clear of debris, ice and snow.

**164.054 General Areas**

- (A) Each building shall have sufficient and separate space for reception and office areas, including:
- (1) reception and waiting areas;
  - (2) administrative and staff offices; and
  - (3) storage of client records.
- (B) Program service areas shall be designated and furnished in a manner consistent with their use and so as to safeguard client confidentiality, dignity and privacy.

- (C) Toxic substances, including medications, cleaning supplies and paints, shall be kept in locked storage areas.

**164.055 Tobacco-Free Environment**

- (A) Tobacco use is prohibited throughout the entire facility with no exceptions, including all indoor space, offices, hallways, waiting rooms, restrooms, elevators, meeting rooms, and community areas, subject to M.G.L. c. 270 §22 for acute care residential substance abuse treatment centers. The prohibition shall include agency-owned and/or leased vehicles, and personal vehicles when used to transport clients. Such prohibition shall apply to everyone, including employees, clients, consumers, contractors, and visitors.
- (B) The licensee may establish restricted exterior smoking areas away from main entrances to the building. The licensee shall establish separate exterior smoking areas, or separate smoking times, for clients and staff.

**164.056 Restrooms**

- (A) Restrooms shall be conveniently located and accessible throughout the building, and shall be designed to:
- (1) permit opening a locked door from the outside in an emergency;
  - (2) ensure privacy through the use of partitions and doors; and
  - (3) provide adequate ventilation through windows and/or by exhaust fans.
- (B) Restrooms shall be cleaned frequently and maintained in good repair and in a sanitary manner.
- (C) Restrooms shall have sufficient supplies, including soap, paper towels, and toilet paper, at all times.
- (D) Licensees shall provide an adequate number of restroom facilities which are adapted for use by and accessible to individuals with disabilities or wheelchairs.
- (E) Restrooms shall be equipped with flashing lights to signal fire or other alarms for hearing impaired persons.

**164.057 Communication Systems**

Licensees shall establish and maintain telephone and electronic equipment necessary to ensure efficient communication for staff and clients. Telephone systems shall include Telecommunication Device for the Deaf (TDD)/Teletypewriter (TTY) equipment, relay systems or other technology approved by the Department.

**164.058 First Aid**

The licensee shall ensure that a first aid kit, equipped as recommended by the American Red Cross, is available at a central, easily accessible location that is clearly marked. The American Red Cross recommends the following: phone number for poison control center, activated charcoal, adhesive tape, antiseptic ointment, band-aids, blanket, cold pack, disposable gloves, gauze pads and roller gauze, hand cleaner, plastic bags, scissors and tweezers, small flashlight and extra batteries, syrup of Ipecac, and triangular bandage.

**164.059 Child Safety**

If children are permitted on the premises for any reason, the licensee shall ensure that children on site are supervised at all times by an adult, and that the premises are safe for children.

(A) Safety provisions shall include:

- (1) floors and walls free from dangerous protruding objects;
- (2) intact banisters and balusters;
- (2) tall or top-heavy furniture bolted to the floor or wall;
- (3) electrical cords secured to baseboard or floor;
- (4) toys in children's play areas sanitized daily with written cleaning procedures posted;
- (5) in facilities with kitchens, children under six shall not be permitted in kitchen areas, and kitchen cabinets and refrigerators shall be equipped with child-proof locking mechanisms;
- (6) protective covers on radiators;
- (7) If children under six years of age are present, provisions shall also include:
  - (a) covers larger than 1x4 inches installed on all electrical outlets;
  - (b) diaper changing areas with a safety strap and adequate supplies for cleaning the surface with a disinfectant after each use;
  - (c) safety bars on windows above the first floor, and on any other hazardous window accessible to children; and
  - (d) gates placed across top and bottom of stairways.

(B) If the licensee provides a separate area for children and restricts children's access to other parts of the premises, provisions under (A) shall apply to the separate children's areas only.

(C) Licensees providing residential care for children under six years of age shall ensure that the premises are free of lead paint.

**164.060 Fire Protection**

The licensee shall provide adequate fire protection equipment and devices appropriate to the needs of the particular building. During the periodic inspection required under 105 CMR 164.050 Required Inspections, the licensee shall consult with the local fire department regarding the selection of protection equipment, such as fire alarms, fire extinguishers, smoke detectors and child protective window devices. The licensee shall provide the devices recommended in the inspection report in a timely manner.

**164.061 Internal Incident Investigation and Reporting**

The licensee shall develop and follow written procedures for conducting internal investigations including, but not limited to, responses to any alleged or suspected incident of physical or sexual assault, abuse or neglect, which occurs at or under circumstances connected with the program. The licensee shall orally inform the Department immediately, and in writing the next business day, of any allegation or incident at or under circumstances connected with the program involving the health or safety of clients. The licensee shall ensure that staff are trained in and understand child abuse and neglect reporting requirements. Such training shall be documented in personnel folders.

**164.062 All Hazard and Emergency Planning & Procedures**

The licensee shall establish a written plan for response to emergencies. Said plan shall be formulated on an all-hazards approach: provide for response to internal, local, community, state, regional or national emergencies, regardless of cause (natural or man-made). The plan shall document the licensee's communications with community emergency management and response agencies. The plan shall include at a minimum the provisions described below.

- (A) Specification of roles and responsibilities of program or agency staff in the event of an emergency, including the sequence of authority in the event executive leadership is unavailable. The chain of command shall describe duties related to emergencies, including:
- (1) internal communication and notification of the emergency;
  - (2) instructions related to use of alarm systems and signals;
  - (3) instructions for evacuation of the building;
  - (4) notification of and liaison to local emergency management and response agencies;
  - (5) where evacuation of the locality is necessary, overseeing evacuation of clients and staff to designated evacuation/relocation sites;
  - (6) ensuring security of program records; and
  - (7) controlling access to the facility.
- (B) Establishment of an emergency communication system specifying responsibility for
- (1) notification of staff;
  - (2) notification of clients; and
  - (3) notification of the Department.
- (C) Identification of local and state emergency management and response agencies, including location, phone numbers and emergency contact information.
- (D) Relocation of staff and clients in the event of an evacuation. Such plan shall identify the local evacuation sites and procedures, and shall specify provisions for evacuation of individuals whose mobility is impaired and/or who require adaptive equipment. The licensee shall determine, and document, any restrictions that may apply to evacuation sites.
- (E) Maintenance of essential services. Licensees who store and/or dispense medications shall include provisions for safe storage of medication as well as for continuity of service to clients.
- (F) Provision for continuity of care for existing clients and patients. Licensees may develop cooperative plans with other substance abuse treatment programs in the community to provide for continuity of care.
- (G) Safe storage and retrieval of program records. This plan shall include provision for regular backup and separate fireproof storage of electronic records.
- (H) Preparation and training of staff and clients through periodic training, including drills, and review of procedures.
- (I) Licensee's response to community need for substance abuse treatment service as a result of the emergency. Said response may be established in coordination with other substance abuse treatment services, programs or facilities in the licensee's community.

**Substance Abuse Treatment Program Requirements: All Licensees**

**164.070 Referrals and Admissions**

- (A) The licensee shall establish written admission eligibility criteria and procedures, and shall make the criteria available to prospective clients upon application for admission. Admission eligibility criteria shall be posted in a conspicuous, public area.

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- (B) The licensee shall apply any restrictions, priorities or special admission criteria equally to all potential admissions regardless of the source of payment, race, gender, creed, ethnic origin or sexual orientation, except that licensees providing a service designed for a specific population, e.g., women or adolescents, may limit admissions to members of that population. The licensee shall comply with applicable state and federal anti-discrimination laws. All individuals applying for admission and clients shall be made aware of these restrictions, priorities or special admission criteria at the time of application.
- (C) Where consistent with the level of care and program of services, admission eligibility criteria shall specifically address priority populations defined by the Department.
- (D) The licensee shall establish in writing a formal admissions procedure for potential new admissions and for re-admissions, including gathering and recording all pertinent information needed to evaluate eligibility and service need, and to complete the Department's information system form(s).
- (E) Individuals who do not meet eligibility requirements or who are inappropriate for the licensee's level of care shall be referred to an appropriate service, person, agency or court. The licensee shall maintain a log of applications denied and referrals made, and shall make this documentation available to the Department for inspection.
- (F) Upon admission into treatment, or as soon as the client is medically cleared, the licensee shall obtain and make a part of the client record:
  - (1) a consent to treatment form signed by the client;
  - (2) name and contact information of a person to contact on client's behalf in an emergency, including client's consent to such contact. Refusal to provide an emergency contact shall be documented in the client's record; and
  - (3) name of client's health insurance carrier.
- (G) The licensee may not deny admission to an individual solely because the individual uses medication prescribed by a physician outside the licensee's service or facility.
- (H) Licensees may deny admission to individuals who refuse to provide information necessary to complete an assessment and treatment plan.
- (I) The licensee may not deny re-admission to any person solely because that person
  - (1) withdrew from treatment against clinical advice on a prior occasion;
  - (2) relapsed from earlier treatment; or
  - (3) filed a grievance regarding an action or decision of the licensee.

**164.071 Orientation**

The licensee shall provide each new or returning client with an orientation that will familiarize him/her with the client's rights, and with rules, procedures, activities, policies, and philosophy of the program, including program requirements for participation, disciplinary action, termination, and grievance procedures. Written orientation materials shall be included in the Client Policy Manual, as required by 105 CMR 164.081 Client Policy Manual. Written documentation of this orientation shall appear in the clinical records.

**164.072 Assessment**

The licensee shall complete an initial assessment for each client that includes the following elements, as well as elements prescribed for each level of care in Part Two of these regulations:

- (A) Appropriateness of licensee's level of care in relation to client's treatment needs.
- (B) A history of the use of alcohol, tobacco and other drugs, including age of onset, duration, patterns and consequences of use; use of alcohol, tobacco and other drugs by family members; and types of and responses to previous treatment.
- (C) An assessment of the client's psychological, social, health, economic, educational/vocational status; criminal history; current legal problems; co-occurring disorders; trauma history; and history of compulsive behaviors such as gambling. The assessment must be completed before a comprehensive service plan is developed for the patient.
- (D) An assessment of the client's HIV risk status.
- (E) An assessment of the client's TB risk status.
- (F) When the initial assessments indicate a need for further evaluation, the program shall conduct or make referral arrangements for necessary testing, physical examination and/or consultation by qualified professionals.
- (G) The initial assessment shall be conducted by a Senior Clinician, Clinician, Physician, Nurse Practitioner or Physician Assistant. If conducted by a Clinician, it must be approved in writing by a Senior Clinician.
- (H) The initial assessment shall conclude with a diagnosis of the status and nature of the client's substance use disorder, using standardized definitions established by the American Psychiatric Association, or a mental or behavioral disorder due to use of psychoactive substances, as defined by the World Health Organization.

**164.073 Individual Treatment Plan**

For each client admitted, the licensee shall complete an individual treatment plan which includes the following elements, as well as elements prescribed for each level of care in Part Two of these regulations.

- (A) The treatment plan, and all subsequent updates, shall include documentation of at a minimum the following information:
  - (1) A statement of the client's strengths, needs, abilities and preferences in relation to his/her substance abuse treatment, described in behavioral terms;
  - (2) Evidence of the client's involvement in formulation of the treatment plan, in the form of the client's signature attesting agreement to the plan;
  - (3) Service to be provided;
  - (4) Service goals, described in behavioral terms, with time lines;
  - (5) Clearly defined staff and client responsibilities and assignments for implementing the plan;
  - (6) Description of discharge plans and aftercare service needs;
  - (7) Aftercare goals;
  - (8) The date the plan was developed and revised;
  - (9) Signatures of staff involved in the formulation or review of the plan; and
  - (10) Documentation of disability, if any, which requires a modification of policies, practices, or procedures and record of any modifications made.
- (B) The licensee shall ensure that individual treatment plans are reviewed with the client and amended as necessary. When treatment continues for three months or more, treatment plans shall be reviewed at least once every three months. The client and staff reviewing the plan shall sign it, and

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it shall be incorporated into the client's record. If there has been no client contact over a three-month period, the client shall be discharged from care and the case closed.

(C) Plans developed or revised by a Counselor shall be reviewed and signed by his/her supervisor.

**164.074 Minimum Treatment Service Requirements**

The licensee shall provide directly, through qualified service organization agreements with Qualified Service Organizations, or through referral, the following services, as well as services prescribed for each level of care in Part Two of these regulations:

- (A) Substance abuse therapies, counseling and education which conform to accepted standards of care;
- (B) HIV education and counseling;
- (C) TB screening, education and treatment;
- (D) Tobacco education and counseling;
- (E) Case management including referrals based on continuum of care and client educational, vocational, financial, legal and housing needs;
- (F) Mental health services, including psychopharmacological services, for individuals with co-occurring disorders;
- (G) Health services, including family planning services requested by the client;
- (H) Services for individuals with compulsive behaviors such as compulsive gambling;
- (I) Relapse prevention and recovery maintenance counseling and education; and
- (J) Planning for client's completion of treatment provided by licensee, and identification of transitional, discharge and aftercare supports the client may require.

**164.075 Termination and Discharge**

(A) The licensee shall establish written termination and discharge policies and procedures and shall make these available to prospective clients at the time of admission. These shall include:

(1) Written criteria defining:

- (a) Successful completion of the program;
- (b) Voluntary termination prior to program completion;
- (c) Involuntary termination; and
- (d) Transfers and referrals.

(2) Procedures for planning the discharge in consultation with the client when one of the following conditions is met:

- (a) Client has received optimum benefit from treatment and further progress requires either the client's return to the community or the client's referral to another type of treatment program;
- (b) The client has achieved the goals of the individual treatment plan.

(3) Components of a discharge summary including:

- (a) Description of services provided;
- (b) Client's substance use at discharge;
- (c) Client's current vocational, educational and financial status;
- (d) Current legal problems;
- (e) Reason for termination;
- (f) Referrals provided;
- (g) Supports and services available to the client after discharge, provided by the licensee or by others;



- (h) Documentation of efforts made by the licensee to prevent discharge of a client to a shelter for the homeless;
  - (i) Documentation of client's participation in discharge planning, or of client's refusal to participate; and
  - (j) An aftercare and follow-up plan including method for contacting client if the client consents to contact.
- (B) The licensee shall establish procedures for discharge if a client leaves the program against clinical advice or is involuntarily discharged from the program including, but not limited to, an appeal process for an involuntary discharge. The licensee shall refer the client to another facility/program for treatment if necessary or appropriate.
- (C) Licensees may discharge clients who refuse to provide information required for necessary coordination of treatment.
- (D) Licensees providing Opioid Treatment Services shall establish additional termination and discharge procedures as specified in 105 CMR 164.309 Involuntary Termination.
- (E) Licensees providing residential services, whether acute or rehabilitation, shall not develop a discharge plan which provides for discharge of a client or patient to a shelter for the homeless.

**164.076 Aftercare**

The licensee shall establish written policies and procedures for provision of aftercare for clients who are discharged, which shall include provisions for client participation in developing the aftercare plan and a method for contacting the client. Aftercare services shall include:

- (A) Referrals to ensure a continuum of care for the client, including arrangements for further substance abuse treatment and post-discharge counseling and other supportive service;
- (B) Information concerning available community-based service agencies and programs, which shall include a description of services, addresses, phone numbers and the names of contact persons;
- (C) Referrals, the aftercare plan and information provided to the client shall be documented in the client's record; and
- (D) If a client refused aftercare services, the licensee shall ensure that the refusal is documented in the client's record.

**164.077 Post-Discharge Follow-Up**

The licensee shall establish written policies and procedures for follow-up client contact. Such policies shall describe circumstances under which a client may be contacted after discharge and shall require that client's permission for such contact be documented in the client's record.

**164.078 Behavior Management**

The licensee shall establish and maintain written policies and procedures for managing disruptive behavior, including aggression, harm or threats of harm to self or others, destruction of property, and refusal to comply with program policies. The policy and procedures shall be posted and shall include:

- (A) Description of the safeguards for the emotional, physical and psychological well-being of the population served;

- (B) A description of measures used to promote appropriate behavior and definition and explanation of behavior management procedures used in the facility including, where applicable:
- (1) level/point systems of privileges, including procedures for the client's progress in the program;
  - (2) the type and range of restrictions a staff member can authorize for misbehavior of residents; and,
  - (3) behavioral interventions to be used in response to angry or aggressive clients, including de-escalation techniques;
- (C) Prohibition of physical restraints in any form; and
- (D) Criteria for the transfer or discharge of any client whose aggressive behavior presents a danger or threat of danger to the resident or to other clients or staff.

**164.079      Clients' Rights**

- (A) The licensee shall safeguard the legal and civil rights of each client at all times during treatment and discharge from treatment. Each licensee shall adopt and maintain an updated set of rules, which set forth the responsibilities and the rights of clients regarding treatment and discharge.
- (B) The licensee shall guarantee the client, at a minimum, the following rights:
- (1) freedom from physical and psychological abuse;
  - (2) freedom from strip searches and body cavity searches;
  - (3) control over his/her bodily appearance, provided, however, on program premises, the licensee may prohibit attire and personal decoration which interfere with treatment;
  - (4) access to his/her client record in the presence of the administrator or designee unless there is a determination that access to parts of the record could cause harm to the client;
  - (5) the right to challenge information in his/her client record by inserting a statement of clarification or letter of correction signed by both the clinician and the client;
  - (6) the right to obtain a copy of the client's records as specified in 105 CMR 164.083: Client Records;
  - (7) the right to have the confidentiality of his/her records secured as required by 105 CMR 164.084: Confidentiality;
  - (8) the right to terminate treatment at any time;
  - (9) freedom from coercion;
  - (10) treatment without regard to race, ethnicity, creed, national origin, religion, sex, sexual orientation, age, or disability;
  - (11) treatment in a manner sensitive to individual needs and which promotes dignity and self-respect;
  - (12) full disclosure regarding fee charged and, in residential rehabilitation programs, any client benefits to be contributed;
  - (13) the right to grieve actions or decisions of the licensee regarding the client's treatment;
  - (14) freedom to practice his or her religious faith;
  - (15) the right to request referral to a facility which provides treatment in a manner to which the client has no religious objection;
  - (16) drug screens conducted in a manner which preserves the client's dignity and, when the drug screen is by urine sample, accommodates any medically confirmed inability to give urine by providing for an alternate effective means of screening such as oral swab; and
  - (17) the right to contact the Department.
- (C) The licensee shall provide for translations of rights, rules and manuals for clients who do not read English.

**164.080**      **Grievances**

The licensee shall establish written policy and procedures for the resolution of clients' disagreement(s) or dispute(s) arising in relation to treatment or program requirements and shall ensure that clients are provided with a copy of the procedures. The policy and procedures shall specify:

- (A) Clients' right to grieve actions and/or decisions of the licensee regarding the client's treatment;
- (B) Steps to be taken to resolve the matter; and
- (C) Provisions for a hearing on the matter presided over by an impartial grievance officer who may be any staff or other person(s) not directly involved in the facts of the incident giving rise to the action grieved or in the decision to commence the action; provided that the persons involved in either the facts of the incident or in the decision to commence the proceedings shall not have authority over the hearing officer(s). Grievance officers shall be selected based upon their expertise in issues being grieved (e.g., medical officer/medical grievance, administrative office/administrative grievance).

**164.081**      **Client Policy Manual**

- (A) Each licensee shall adopt and maintain a current policy manual for clients containing clear and concise statements regarding:
  - (1) Program description including:
    - (a) goals and objectives,
    - (b) type of services provided including aftercare and follow-up;
    - (c) qualifications for service delivery staff;
    - (d) restrictive criteria for receipt of specific services, if any;
    - (e) scheduling restrictions; and
    - (f) overall hours of program operation;
  - (2) Orientation materials provided to clients at admission;
  - (3) Admission requirements and intake procedures, including a list of the minimum information that is collected at the intake session:
    - (a) social, economic, and family history;
    - (b) educational and vocational achievement;
    - (c) criminal history; and
    - (d) medical, drug, and drug-treatment histories;
  - (4) Fee policies including:
    - (a) reduced fees for persons of low income; and
    - (b) whether or not the program accepts public or private third-party reimbursement or funding;
  - (5) Procedures regulating access to client records;
  - (6) Program rules, including:
    - (a) all obligations imposed on clients and sanctions for their violation;
    - (b) restrictions on use of tobacco products;
    - (c) criteria for termination;
    - (d) procedures for involuntary terminations;
    - (e) grievance procedure for the resolution of any other client related problem or dispute.
  - (7) Policies, practices, and procedures for the disabled; and
  - (8) Clients' rights.
- (B) The policy manual shall be made available to all clients and/or interested parties as follows:
  - (1) placed visibly in a public area frequented by all clients or kept at a central location, with a notice of its availability conspicuously posted in a public area frequented by all clients; and

- (2) given to each new client during the admission process or subsequently upon his/her request, and to any interested party upon request.
- (C) Whenever the licensee makes a change in policy, it shall issue a written change to the policy manual; the change shall not take effect until placed in the manual and distributed as provided for in 164.081 (B) above.
- (D) When furnishing a client with a copy of the policy manual or of any changes to the policy manual, the licensee shall secure a dated and signed receipt, which shall be placed in the client record.
- (E) The licensee may charge for the cost of copying and assembling the policy manual for an interested party or for a second copy to a client.

**164.082 Special Populations**

Licensees providing services to special populations listed below shall make additional provisions as specified:

- (A) **Pregnant Women:** Licensees serving pregnant women shall:
  - (1) establish in writing clinically appropriate medical protocols for pregnant women;
  - (2) designate a hospital for emergency obstetrical and medical back-up; however, clients may elect to choose their own medical providers;
  - (3) either directly or through qualified service organization agreements provide for appropriate parent-child services; and
  - (4) be available to serve women in all three trimesters of pregnancy.
- (B) **Persons under 18 years of age:** Licensees serving persons under 18 years of age shall:
  - (1) ensure that assessments as required in 105 CMR 164.072 include a evaluation of:
    - (a) developmentally age-appropriate behaviors;
    - (b) cognitive functioning;
    - (c) physical maturation; and
    - (d) peer group functioning, including education and social maturity;
  - (2) determine the person's legal status;
  - (3) ensure that staff providing services for children and adolescents have specific training in child and teen development, including a minimum of five college credit hours in courses related to the topic;
  - (4) ensure that services for adolescents are supervised by a Senior Clinician with at least two years post-master's experience working with adolescents with substance use disorders;
  - (5) ensure that adolescents are served in programs which are separate from programs serving adult populations; and
  - (6) prior to providing any services to persons under 18, inform the Department of the nature and scope of any services provided to adults in the same facility as those intended for services for adolescents. The Department shall determine whether such proximity of adult services constitutes a risk to adolescents.
- (C) **Persons with co-occurring disorders:** Licensees serving persons with co-occurring disorders shall
  - (1) establish policies and procedures for referrals for specialized psychiatric/psychological care; and
  - (2) establish Qualified Service Organization agreements providing for mental health interventions and coordinated care.
- (D) **Elders:** Licensees serving persons age 60 and over shall establish Qualified Service Organization agreements with local organizations providing services for the elderly.

- (E) **Persons with Disabilities:** Licensees serving persons with disabilities shall document the client's current functioning, ability to perform activities of daily living, and ability to comprehend program policies and procedures.

**164.083      Client Records**

- (A) The licensee shall maintain separate records for each client in a secure and confidential manner. Records shall be legible and up to date no later than five business days from the date of last client contact.
- (B) The written individual client record shall include, but not be limited to, the following information:
- (1) name, unique client identifier, date of birth, sex, race/ethnicity, relationship status, and primary language, if other than English;
  - (2) name and contact information of the referring agency, court or person;
  - (3) presenting problem(s);
  - (4) all necessary authorizations and consents and updates;
  - (5) complete initial assessment as required by 105 CMR 164.072 Assessment;
  - (6) sources of financial support, including insurance coverage information;
  - (7) original service plan and service plan reviews;
  - (8) signed client confirmation of receipt of agency policy manual and information regarding maintenance of client confidentiality;
  - (9) signed and dated progress notes entered by client's counselor after every client contact or attempted contact;
  - (10) documentation of STD, TB, Viral Hepatitis, HIV/AIDS risk assessment;
  - (11) documentation of STD, TB, Viral Hepatitis, HIV/AIDS education;
  - (12) record of any threat made by client to harm self or another, and the action taken by licensee in response to threat(s);
  - (13) record of multidisciplinary team reviews concerning client;
  - (14) discharge summary;
  - (15) aftercare service plan; and,
  - (16) record of attempts at follow-up by letter, phone call, home visit or through contacts with aftercare providers.
- (C) Progress notes shall be current, legible, dated, and signed by the individual making the entry. Group counseling and educational-session progress notes may describe the session in general, but the client's record must also include in each progress note specific comments on the client's participation and progress in the group.
- (D) All client cases reviewed by a Clinician and Counselor shall receive a quarterly record review by his/her supervisor. Evidence of this review shall be documented in the clinical record.
- (E) All client records shall be marked confidential and kept in a secure, locked location, accessible only to authorized staff. Electronic records shall be secured through firewall and password protection and shall be accessible only to authorized staff.
- (F) Except as otherwise provided in 105 CMR 164.00 or by applicable state or federal law, access to client records shall be limited to the client or his/her designee pursuant to client's written authorization, and to those staff members authorized by the administrator. The licensee shall have a written procedure regulating and controlling access to client records by staff members whose responsibilities require access.
- (G) Upon a client's request, the licensee shall provide, in a timely manner, to the client, another licensee or other specifically authorized person:
- (1) The opportunity to inspect the client's records;

- (2) A copy of such record, except in circumstances described in 243 CMR 2.07(13)(e) governing licensed physicians engaged in the practice of psychiatry;
- (3) A copy of any previously completed report required for third party reimbursement.

- (H) The Department shall have access to client records for the purposes of reviews required under these regulations. The licensee shall obtain any signed consent from its clients that it deems necessary to provide such access.

**164.084 Confidentiality**

Client-specific information shall be privileged and confidential and shall be made available only in conformity with all applicable state and federal laws and regulations regarding the confidentiality of client records, including but not limited to, 42 CFR Part 2, and 45 CFR Parts 160 and 164 (HIPAA Privacy and Security Rules) if applicable.

- (A) The licensee shall, as part of its orientation, inform and train all staff members, in writing, of these confidentiality requirements. Evidence of this notification and training shall be included in personnel records.
- (B) The licensee shall, as part of its client orientation, inform all clients in writing of these confidentiality requirements. Evidence of the provision of this information shall be included in the client's record.
- (C) The licensee shall have written policies and procedures controlling access to records and to information pertaining to HIV/AIDS and HIV/AIDS testing pursuant to M.G.L. c. 111, § 70F.

**164.085 Transfer and Storage of Service Records**

- (A) The licensee shall maintain client records in a secure place for seven years from the date of client's termination of services unless required by law to do so for a longer period. Programs licensed as a hospital or clinic shall maintain client medical records for 30 years pursuant to M.G.L. c. 111, § 70. The licensee shall ensure that clinical records accompany clients upon transfer. Transfer of records shall be made in accordance with federal and state confidentiality law and regulations. A signed consent from each client must be obtained prior to the transfer of such records.
- (B) When closing a program, service or facility, the licensee shall ensure that all records not transferred to a new facility with the client be securely stored for the remainder of the 7 year period mandated for each record. For all current clients of the licensee at the time of closure, the licensee shall also make every effort to provide a copy of the record to the client at the time of closure, if the record is not transferred with the client to a new treatment program. Public notice shall be given regarding the date of service termination and the site at which such records shall be securely stored. The licensee shall prepay the full cost of such storage and shall contract to ensure that the records are appropriately maintained for the entire period and that the records are destroyed at the end of the period in a manner that protects their confidential nature.

**164.086 Interruption or Suspension of Service**

- (A) If a licensee notifies the Department pursuant to 105 CMR 164.035(D) or (H) that the health, safety or well-being of clients is in imminent danger as a result of conditions existing within the service, program or facility, the licensee shall consult with the Department to determine whether there is a need to interrupt or suspend a service or program.
- (B) If the Department determines there is a need to interrupt or suspend a service or program as provided for in 105 CMR 164.018 : Grounds for Suspension of a License, the licensee shall:

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- (1) notify clients of the interruption or suspension;
  - (2) provide for continuity of care for clients during the period of interruption or suspension; and,
  - (3) provide for the secure storage or safe transfer of client records, with client authorization.
- (C) Within five (5) days of the interruption or suspension of services or program, the licensee shall notify the Department in writing of its plans for resumption of service, or for transfer of services to another program or facility.

**164.087**      **Closure**

- (A) The licensee shall notify each client orally and in writing at least 30 days prior to the termination of service or program that the service or program will close, and document the notification in each client's record. Notification shall specify the date of closure. If fewer than 30 days remain prior to an involuntary closure, licensee shall cooperate with the Department to ensure appropriate notice.
- (B) The licensee shall develop a written referral plan in collaboration with each client that includes a plan for continuing the client's substance abuse treatment, including referrals for continued treatment, if appropriate. If insufficient time remains to ensure an appropriate referral plan with respect to an involuntary closure, the licensee shall cooperate with the Department and the client to ensure an appropriate referral, if required.
- (C) The Department may, in exceptional circumstances, grant permission for the temporary closure of the service or program for a period no longer than 30 days when the Department finds that clients will not be affected adversely by the temporary closure.

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**PART TWO: LEVELS OF CARE**



**164.100 ACUTE SERVICES**

**164.101 Scope**

Acute Services encompass levels of care to persons who are intoxicated or incapacitated by their use of alcohol and/or other drugs. The primary purposes of acute services are management and treatment of withdrawal from alcohol and/or other drugs. Acute services include encouragement of the patient's continued participation in treatment after discharge, and conclude with a referral for other recovery and rehabilitation services.

**164.111 ACUPUNCTURE**

**164.112 Scope**

Provisions of 105 CMR 164.113 through 164.115 apply to acupuncture substance abuse detoxification services. The licensee shall also comply with all provisions of Part One of these regulations.

**164.113 Provision of Services**

(A) Admission: Prior to admission, the licensee shall determine that acupuncture services are appropriate based on:

- (1) existence of a substance use disorder or a mental or behavioral disorder attributable to psychoactive substance use; and
- (2) absence of current or potential withdrawal symptoms which constitute a risk to the patient's health and well-being and which require medical attention or medical monitoring.

(B) Assessment: In addition to the assessment required by 105 CMR 164.072, the licensee shall conduct a screening to determine that acupuncture is not contraindicated. The screening shall include, at a minimum:

- (1) client's history of seizures, delirium tremens or other life-threatening withdrawal symptoms, which constitute a risk to the client's health or well-being;
- (2) neurological evidence of an appropriate level of consciousness; and
- (3) vital signs.

(C) Treatment: The licensee shall provide:

- (1) intensive acupuncture administration of six treatments per week for detoxification purposes, followed by less intensive treatment of two to three times per week for relapse prevention;
- (2) a primary counselor to provide case management and motivational counseling that focus on engaging the client to remain in acupuncture treatment;
- (3) supportive counseling during the relapse prevention phase to motivate the client to utilize ongoing substance abuse outpatient treatment and self help groups. Supportive counseling sessions shall include HIV risk assessment and AIDS education; and
- (4) outreach services to attract underserved target populations, maintain client census, and develop linkages with community agencies.

**164.114 Staffing Pattern**

The licensee shall establish a staffing pattern in sufficient numbers and positions necessary for the level of care provided. Staffing pattern shall include the following positions:

- (A) An acupuncturist on site during the hours of operation.
- (B) Consultation to staff available from a fully qualified clinician, and a physician, psychiatrist, nurse practitioner, physician assistant, registered nurse or licensed practical nurse either on-site or through an affiliation agreement. If services are to be available through a Qualified Service Organization (QSO) Agreement, the QSO agreement shall be reaffirmed every two years.
- (C) Supervision: In addition to supervision requirements set forth in 105 CMR 164.044 Training and Supervision, the licensees shall ensure that supervision of nursing staff is overseen by a registered nurse.

**164.115 Hours of Operation**

The licensee shall provide service a minimum of six days per week, 52 weeks per year. Daytime hours shall include morning services and ensure maximum accessibility to clients without an appointment. Hours shall include at least seven hours per week that shall be at time other than the regular 9:00 A.M. to 5:00 P.M., Monday through Friday schedule.

**164.121 OUTPATIENT DETOXIFICATION**

**164.122 Scope**

Provisions of 105 CMR 164.123 through 164.125 apply to outpatient substance abuse detoxification treatment services. The licensee shall also comply with all provisions of Part One of these regulations.

**164.123 Provision of Service**

- (A) Admission: Prior to admitting a client into outpatient detoxification treatment, the licensee shall obtain and shall make a part of the client record a medical evaluation by a licensed physician, psychiatrist, registered nurse, nurse practitioner, physician assistant or licensed practical nurse, which confirms that the client requires outpatient detoxification services based on:
  - (1) an assessment of the current and potential withdrawal symptoms of the client;
  - (2) the client's need for a structured program with frequent contact in order to engage in treatment; and,
  - (3) an assessment as to whether the community in which the client resides poses a threat to the client's abstinence.
- (B) Physical Examination: The licensee shall ensure that a thorough physical examination, which conforms to principles established by the American Society of Addiction Medicine, is completed for all patients within 24 hours of admission.
  - (1) The physical examination shall include:
    - (a) an assessment of the patient's substance use disorder;
    - (b) tests for the presence of opiates, alcohol, benzodiazepines, cocaine and other drugs of abuse as indicated by the patient's current substance use;
    - (c) a brief mental status exam;
    - (d) an assessment of infectious diseases, including TB, Viral Hepatitis, and sexually transmitted diseases (STDs); pulmonary, liver, and cardiac abnormalities; dermatological and neurological sequelae of addiction; and possible concurrent surgical problems. When indicated, laboratory tests for these conditions shall be ordered.

The licensee shall ensure that laboratory tests are completed by licensed facilities that comply with all applicable federal and state licensure and certification requirements.

- (2) The licensee shall ensure that the patient's current prescription medications are assessed in relation to interactions with medication prescribed in the course of treatment. Prior to prescribing, dispensing or administering an approved opioid agonist medication, the licensee shall ensure that the approved medication is not contraindicated by the patient's current prescribed medications or health status.
- (3) For women of child-bearing age, the licensee shall include a pregnancy test in the physical examination.
- (4) If the examination is conducted by a qualified health care professional who is not a physician, the results of the examination and any recommendations arising from the examination shall be reviewed by the nursing supervisor prior to implementation.
- (5) All medical orders shall be signed by the medical director.
- (6) When re-admitting a patient who had been admitted within the previous three months, the timing, frequency and interval of a complete physical examination shall be subject to physician discretion, provided that no more than three months elapses between physical examinations.

(C) Treatment:

- (1) The licensee shall provide detoxification services after determining through physical examination that such services are required.
- (2) Upon receiving medical clearance to participate in treatment services, the licensee shall provide each client with at least 9 hours of service programming each week.
- (3) Treatment shall include services specified in 105 CMR 164.074 Minimum Treatment Service Requirements, and shall be provided either directly or through Qualified Service Organization agreements.

164.124      Staffing Pattern

- (A) The licensee shall designate a physician as Medical Director who shall be responsible for administering all medical services performed by the program. The Medical Director shall have, at a minimum, six months' clinical experience with alcohol and other drug-dependent persons or 40 hours of documented continuing education credit in treating addicted persons within the first twelve months of employment. The Medical Director shall be responsible for:
  - (1) Ensuring that each patient receives a complete physical examination including a medical history;
  - (2) Ensuring that appropriate laboratory studies have been performed; and,
  - (3) Signing all medical orders.
- (B) The licensee shall establish a staffing pattern in sufficient numbers and positions necessary for the level of care provided. Staffing pattern shall include the following positions:
  - (1) Senior Clinician among direct service staff, who shall be responsible for the clinical/educational operation of the substance abuse service;
  - (2) Licensed psychiatrist or licensed psychologist on staff or available through Qualified Service Organization Agreements;

- (3) Registered nurse, nurse practitioner, or physician assistant on staff and on site during hours of operation of the service;
  - (4) Licensed practical nurse, case aides and case management staff;
  - (5) If serving pregnant women, an obstetrician/gynecologist available on staff or through a Qualified Service Organization Agreement; and
  - (6) Sufficient staff to ensure coverage on all shifts.
- (C) Supervision: In addition to supervision requirements set forth in 105 CMR 164.044 Training and Supervision, the licensee shall ensure that supervision of nursing staff is overseen by a registered nurse.
- (D) The licensee shall ensure that a qualified physician is available during all hours when service is provided, either on site or through a Qualified Service Organization Agreement, to provide consultation to staff. If services are to be available through an agreement, this agreement shall be reaffirmed every two years.

**164.125 Hours of Operation**

The program shall be open to provide admission to outpatient services as well as to provide treatment seven days per week and four hours per day, at a minimum.

**164.131 INPATIENT DETOXIFICATION SERVICES**

**164.132 Scope**

Provisions of 105 CMR 164.133 through 164.142 apply to acute care inpatient substance abuse detoxification treatment services. The licensee shall also comply with all provisions of Part One of these regulations.

**164.133 Provision of Services**

**(A) Admission:**

**(1) Determination of Level of Care:**

**(a) Medically Managed Intensive Inpatient Detoxification Services:**

- 1. Level of Care: Medically managed intensive inpatient detoxification services are provided in a hospital setting and include daily medical management and primary nursing interventions.
- 2. Admission Criteria: At the time of admission, the licensee shall determine that the patient requires this level of care because:
  - (i) current and potential withdrawal symptoms are severe, constitute a risk to the patient's health and well-being and require frequent medical attention; and
  - (ii) the patient's incapacity results from a substance use disorder or a mental or behavioral disorder due to psychoactive substance use.

**(b) Medically Monitored Inpatient Detoxification Services:**

- 1. Level of Care: Medically monitored inpatient detoxification services are provided in a medical setting and include 24-hour, 7-day per week nursing and medical supervision.
- 2. Admission Criteria: At the time of admission, the licensee shall determine that the patient requires this level of care because:
  - (i) the patient's current or potential withdrawal symptoms constitute a risk to the patient's health and well-being and require medical monitoring; and
  - (ii) the patient's incapacity results from a substance use disorder or a mental or behavioral disorder due to psychoactive substance use.

- (c) **Clinically Managed Detoxification:**
1. **Level of Care:** Clinically managed detoxification services are provided in a non-medical setting and include 24 hour per day supervision, observation and support, including at least 4 hours of nursing services each day, 7 days each week.
  2. **Admission Criteria:** At the time of admission, the licensee shall determine that the patient requires this level of care because:
    - (i) the patient's current and potential withdrawal symptoms are not severe; and
    - (ii) the patient's incapacity results from a substance use disorder or a mental or behavioral disorder due to psychoactive substance use.
- (2) **Initial Physical Assessment:** Immediately upon admission a brief physical assessment of the patient shall be made by a qualified health care professional.
- (B) **Assessments.** In addition to the initial assessment required by 105 CMR 164.072, the licensee shall ensure that a thorough physical examination, which conforms to principles established by the American Society of Addiction Medicine, is completed for all patients within 24 hours of admission.
- (1) **The physical examination shall include:**
- (a) an assessment of the patient's substance use disorder;
  - (b) tests for the presence of opiates, alcohol, benzodiazepines, cocaine and other drugs of abuse as indicated by the patient's current substance use;
  - (c) a brief mental status exam; and
  - (d) an assessment of infectious diseases, including TB, Viral Hepatitis and sexually transmitted diseases (STDs); pulmonary, liver, and cardiac abnormalities; dermatological and neurological sequelae of addiction; and possible concurrent surgical problems. When indicated, laboratory tests for these conditions shall be ordered.
- The licensee shall ensure that laboratory tests are completed by licensed facilities that comply with all applicable federal and state licensure and certification requirements.
- (2) The licensee shall also ensure that the patient's current prescription medications are assessed in relation to interactions with medication prescribed in the course of treatment. Prior to prescribing, dispensing or administering an approved opioid agonist medication the licensee shall ensure that the approved medication is not contraindicated by the patient's current prescribed medications or health status.
  - (3) For women of child bearing age, the licensee shall include a pregnancy test in the physical examination.
  - (4) If the examination is conducted by a qualified health care professional who is not a physician, the results of the examination and any recommendations arising from the examination shall be reviewed by the medical director prior to implementation.
  - (5) All medical orders shall be signed by the medical director.
  - (6) When re-admitting a patient who had been admitted within the previous three months, the timing, frequency and interval of a complete physical examination shall be subject to physician discretion, providing that no more than three months elapse between physical examinations.
  - (7) If, within 30 days of admission to inpatient detoxification treatment, a patient is transferred to a different level of detoxification care, the licensee to whom the patient is transferred shall, with the patient's consent, request:

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- (a) results of the physical examination described in 105 CMR 164.133 (B)(1) above, and,
  - (b) for women of child bearing age, results of the pregnancy and related tests described in 105 CMR 164.133 (B)(3) above.
- (C) **Additional Medical Services for Opioid Treatment:** Where a full or partial opioid agonist or antagonist medication is dispensed, the licensee shall comply with requirements described in 105 CMR 164.300 et seq.
- (D) **Treatment Services:**
- (1) The licensee shall provide detoxification services as determined by the physical examination.
  - (2) Once the patient receives medical clearance to participate, the licensee shall provide the patient with at least 4 hours of service programming each day. The programming shall include services specified in 105 CMR 164.074 Minimum Treatment Service Requirements, and may be provided directly or through Qualified Service Organization Agreements.
  - (3) The licensee shall provide at least one multidisciplinary team review for each patient stay.
- (E) **Termination and Discharge:** In addition to the termination and discharge requirements delineated in 105 CMR 164.075, the licensee's written procedures shall include the following provisions and shall incorporate these provisions into the policies as described in 105 CMR 164.040 Written Policies and 105 CMR 164.081 Client Policy Manual:
- (1) Criteria for medical discharge;
  - (2) Procedures for emergency and involuntary terminations in accordance with the following:
    - (a) In an emergency situation, where the patient's continuation in the program presents an immediate and substantial threat of physical harm to other patients, program personnel or property or where the continued treatment of a patient presents a serious medical risk to the patient as determined by the medical director or the nurse-in-charge, the licensee may suspend a patient immediately and without provision for further detoxification. The patient shall be afforded the right to an appeal as described in the program policies and as required by 105 CMR 164.080 Grievances.
    - (b) In a non-emergency situation, wherein the patient's continuation does not present the immediate and substantial threat or serious medical risk described in 105 CMR 164.133 (E)(2)(a), the licensee may not terminate the patient without first affording the patient the procedural rights defined in 105 CMR 164.079 Client Rights and 164.080 Grievances.

**164.134 Staffing Pattern**

- (A) The licensee shall designate a physician as Medical Director who shall be responsible for administering all medical services performed by the program. The Medical Director shall have completed a minimum of six months' clinical experience with alcohol and other drug-dependent persons or 40 hours of documented continuing education credit in treating addicted persons within the first twelve months of employment. The Medical Director shall be responsible for:
- (1) Ensuring that each patient receives a medical evaluation, including a medical history;
  - (2) Ensuring that appropriate laboratory studies have been performed; and
  - (3) Signing all medical orders.
- (B) The licensee shall establish a staffing pattern in sufficient numbers and positions necessary for the level of care provided. Staffing pattern shall include the following positions:

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- (1) A full-time equivalent Senior Clinician among direct service staff who shall be responsible for the clinical/educational operation of the substance abuse service;
  - (2) Licensed psychiatrist or licensed psychologist on staff or available through Qualified Service Organization Agreements;
  - (3) Registered nurse, nurse practitioner, or physician assistant;
  - (4) Licensed practical nurse, case aides and case management staff;
  - (5) If serving pregnant women, an obstetrician/gynecologist available on staff or through a Qualified Service Organization Agreement;
  - (6) Food personnel trained in safe and sanitary food handling and preparation, as specified in 105 CMR 590.000 Minimum Sanitation Standards for Food Establishments, §590.003 Management and Personnel. Food service permits, where required, shall be current and available for review by Department personnel; and
  - (7) Sufficient staff to ensure coverage on all shifts.
- (C) Supervision: In addition to supervision requirements set forth in 105 CMR 164.044 Training and Supervision, the licensee shall ensure that supervision of nursing staff is overseen by a registered nurse.
- (D) The licensee shall ensure that a qualified physician is available 24 hours per day, seven days per week, either on site or through a Qualified Service Organization Agreement, to provide consultation to staff. If services are to be available through an agreement, this agreement shall be reaffirmed every two years.

**164.135 Hours of Operation**

The licensee shall provide admission and detoxification services 24 hours a day, seven days per week.

**164.136 Licensure**

A licensee providing medically managed inpatient detoxification services shall be licensed according to the standards described in 105 CMR 164.012(D).

**164.137 Physical Plant**

- (A) Building Design: Each program shall provide adequate space to accommodate the number of patients served, including sufficient and separate space for the following, which may not be used as bedrooms for patients or staff:
- (1) Individual and group counseling sessions;
  - (2) A living room or common area;
  - (3) A visiting area;
  - (4) A kitchen area and a dining area;
  - (5) Recreation and/or exercise area.
- (B) Compliance with Building Standards: The licensee shall ensure that:
- (1) The facility complies with standards specified in 105 CMR 410.000 Standards of Fitness for Human Habitation, regarding heating, electricity, lighting, plumbing and sanitary facilities; and
  - (2) The heating system conforms to requirements defined by the Department of Public Safety (520 CMR, 522 CMR, and 527 CMR) under M.G.L. c. 148.
- (C) Bathrooms and Personal Hygiene: The licensee shall ensure that:
- (1) Female and male patients have separate toilet and bathroom facilities;

- (2) All rooms containing toilets, bathtubs and/or showers are equipped with a door, and have ventilation to the outside through a window or extractor vent;
- (3) No room containing a toilet or shower is so located as to require passing through to go from one area of the premises to another;
- (4) There is at least one toilet for every eight women (1:8) and one toilet for every ten men (1:10), and one washbasin and one shower or tub for every ten individuals (1:10);
- (5) Washbasins are located in the same room as or in close proximity to toilets; a kitchen sink may not be substituted for a washbasin;
- (6) All showers and tubs are equipped with a non-slip surface or mat;
- (7) All toilets have seats;
- (8) Sanitary hand washing requirements and procedures are posted in restrooms, and the licensee familiarizes staff and patients with these procedures;
- (9) Restrooms are maintained in good repair and sanitary manner, cleaned daily, and supplied with sufficient soap, paper towels and toilet paper at all times.

(D) **Sleeping Rooms:** The licensee shall ensure that:

- (1) All sleeping rooms are conveniently located near toilet and bathing facilities. Accessible facilities shall conform to the American with Disability Act regulations.
- (2) Female and male residents have separate sleeping quarters.
- (3) Sleeping rooms are designed to promote comfort and provide adequate space and privacy, and meet the following requirements:
  - (a) no sleeping room shall be less than 70 square feet;
  - (b) rooms accommodating more than one person shall have a minimum of fifty (50) square feet per person;
  - (b) accommodate no more than six persons per sleeping area;
  - (c) have windows or skylights providing natural light and ventilation in compliance with 105 CMR 410.250 and 105 CMR 410.280;
  - (d) a separate bed for each patient;
  - (e) may not be an unfinished attic, stairway, hall or room commonly used for other purposes.
- (4) The sleeping area has the following basic equipment and supplies:
  - (a) a twin size bed with a twin-size mattress and waterproof mattress cover. Cots may not be used;
  - (b) adequate drawer and closet space;
  - (c) an adequate supply of bed linens, blankets, pillows, washcloths and towels, which are in good condition. Linens, blankets, washcloths and towels shall be laundered before each new admission, or once a week, whichever occurs sooner;
  - (d) a toothbrush, toothpaste and basic hygiene supplies;

**164.138 Meals and Food Handling**

- (A) **Inspections:** The licensees shall ensure that food storage and preparation areas meet the standards defined in 105 CMR 590.000: Minimum Standards for Food Establishments, and that the food service is inspected and receives a food service permit by the local board of health, where applicable.
- (B) **Purchased Food Services:** A licensee shall purchase only from a licensed food service establishment. A licensee that purchases from a food service shall obtain from the food service provider documentation of all required inspections, licenses, and conformance with sanitary standards. Such documentation shall include copies of a current license and the most recent inspection report.
- (C) **Meals:** The licensee shall provide a nourishing well-balanced diet to all patients, and shall provide the following:



- (1) Dining areas that are clean, well lighted, ventilated and appropriately furnished.
- (2) A dining room large enough so that all patients may eat at an appropriate hour, but not necessarily simultaneously.
- (3) Three meals each day.
- (4) Food and beverages for snacks.
- (5) Menus for each week planned prior to the start of the week, dated and maintained for 3 months.
- (6) Means to provide for patients with special dietary needs, including food allergies.

**164.139 Safe Storage and Administration of Medications**

- (A) Licensees providing medically managed or medically monitored detoxification services shall ensure that management, storage and administration of medication comply with requirements established by accreditation standards and by the United States Drug Enforcement Agency and Food and Drug Administration.
- (B) Licensees providing clinically managed detoxification services shall comply with the following:
- (1) **Written Policy and Procedure:** The licensee shall establish a written policy and procedure governing the storage and administration of patients' prescription medications.
  - (2) **Storage:** All medications shall be maintained in a locked, secure cabinet, accessible only to designated staff positions. The titles of designated positions shall be posted on the cabinet. The licensee shall ensure that patients do not have direct access to the medication cabinet.
  - (3) **Approval of Medication:** The licensee shall take possession of a patient's prescription and over-the-counter medication upon admission. The medical director shall assess such medication(s) in light of the medical examination and medical services to be provided to determine whether the patient should continue to take these medications.
  - (4) **Medications brought by patients to the program** shall be stored in a locked, secure cabinet that is separate from the facility's supply, except that patients shall retain medications required to treat acute episodes, such as asthma attacks or allergic reactions.
    - (a) If injectable drugs are used, licensees shall provide containers for safe storage, and proper disposal of sharps.
    - (b) Medications requiring refrigeration shall be kept in a refrigerator in the same area where other medications are stored. Medications shall not be stored in kitchen refrigerators.
    - (c) The licensee shall also establish a record of medications which remain in the possession of patients for treatment of acute episodes.
  - (5) **Prescription medication presented by a patient** shall bear a pharmacy label, which shows the date of filling, the pharmacy name and address, the filling pharmacist's initials, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, the name of the prescribed medication, directions for use and cautionary statements, if any, contained in such prescription or required by law, and if tablets or capsules, the number in the container. All over-the-counter medications shall be kept in the original containers containing the original label, which shall include the directions for use.
  - (6) Upon admission the licensee shall document in writing the number of tablets or capsules, or the approximate amount of liquid in each prescribed medication brought by the patient. The licensee shall ensure that a similar count is conducted by two staff persons at the beginning of each shift.

- (7) The licensee shall maintain documentation of all medications stored and disposed of.
- (8) **Self-Administration of Medications:** Medications shall be self-administered by the patient, unless the licensee employs qualified health care professionals authorized to administer medications. Patients must be able to administer their own medications, and, unless the licensee employs qualified health care professionals for this purpose, staff shall not administer medication to any patient. However, staff shall observe the patient ingesting the prescribed dose. Medications may not be provided to any patient if other patients are in the storage or office area. Licensees shall make provision to provide a supply of medications to patients who plan to be absent from the facility when they would normally take a medication. The licensee shall maintain documentation of all administrations of medication, which shall include:
- (a) Name of patient to whom medication was provided;
  - (b) Name of staff person observing the patient take the medication, or providing needed supply;
  - (c) Date and time medication was provided; and
  - (d) Patient initials confirming that the medication was provided and taken.
- (9) **Disposing of Medications:** The licensee shall not permit expired medications, medications left behind by patients, or unused medications to accumulate in the storage area. The licensee shall establish policy and procedure for return of patient's medication upon discharge and for safe disposal of medications.
- (10) **Improper Use:** The licensee shall establish a policy regarding improper use of medication which:
- (a) may impose sanctions on patients who do not take medications in accordance with prescribed dose and frequency; and
  - (b) shall impose sanctions on patients who illegally obtain and use prescription medications.

**164.140 Patient Personal Effects and Affairs**

- (A) **Written Policy and Procedure:** The licensee shall establish a written policy and procedure governing care of patient personal belongings and support of patient personal affairs.
- (B) **Safekeeping:** The licensee may allow patients to bring monies and valuables into the program, if the licensee provides for the secure, locked storage of the personal property.
- (C) **Right to Confiscate:** All patients shall be notified that by accepting admission they authorize the licensee to:
- (1) confiscate and dispose of any alcohol or drugs (other than those properly provided by prescription) or paraphernalia for the use of illegal drugs found in the possession of the patient;
  - (2) confiscate any weapons or other articles found in the possession of the patient, which may constitute a threat to the life, health or safety of the patient, the staff or public, and to turn over any guns to the police.
- The licensee shall establish a record of any items confiscated or turned over to the police.
- (D) The licensee shall establish written procedures governing patients' use of telephones, pagers, cell phones or other communication devices, and sending and receiving mail. The licensee may not hold mail or restrict the sending of mail. The licensee may not open residents' mail, but may require that residents open letters or packages in the presence of staff. Alcohol, drugs or weapons shall be confiscated by the program.

**164.141 Back-Up and Transfer Agreements**

**Licensees providing medically monitored or clinically managed detoxification services shall have Qualified Service Organization Agreements for the provision of the following services as needed:**

- (A) Psychiatric consultative, diagnostic and evaluative services;**
- (B) Acute in-patient medical or psychiatric hospitalization;**
- (C) Emergency medical and psychiatric services;**
- (D) Any specialized services that a program provides through special arrangement, purchase or contract.**

**164.142      Death of a Patient**

**The licensee shall develop procedures to be followed in the event of the death of a patient. These procedures shall conform with laws governing the report of death to local authorities, and shall include the following:**

- (A) Local emergency services (911) shall be notified immediately.**
- (B) The licensee shall comply with all laws concerning declaration of death and moving the deceased.**
- (C) The licensee shall make reasonable efforts to notify the deceased's emergency contact. A written record of these efforts shall be included in the patient's record.**

**164.200 OUTPATIENT SERVICES**

Outpatient Services encompass levels of care to persons not at risk of suffering withdrawal symptoms, and who can participate in organized ambulatory services including intensive day treatment services, counseling, and educational services for driving under the influence first offenders.

**164.201 Scope**

Provisions of 105 CMR 164.211 through 164.234 apply to outpatient substance abuse treatment services, including Driver Alcohol Education services. The licensee shall also comply with all provisions of Part One of these regulations.

**164.211 FIRST OFFENDER DRIVER ALCOHOL EDUCATION**

**164.212 Provision of Services**

**(A) Admission and Referral:**

- (1) Referral: The licensee shall admit clients referred by a Massachusetts court, or, for clients under the age of 21, by the Registrar of Motor Vehicles, as provided for by M.G.L. c. 90, §24P.
- (2) Level of Care: Individuals admitted for first offender driver alcohol education services are not required to have a substance use disorder diagnosis.

**(B) Assessment:**

- (1) The licensee shall ensure that the assessment required by 105 CMR 164.072 is completed during the first meeting with the client.
- (2) When admitting a client under the age of 21, the licensee shall also assess the client's developmental status, including social, emotional and cognitive functioning, to determine whether the client is able to participate in programming designed for adults.
- (3) All assessments shall use a standardized addiction assessment instrument approved by the Department.

**(C) Treatment: The licensee shall provide treatment service to each client in accordance with protocols established by the Department. Services shall include:**

- (1) Group education sessions which address:
  - (a) consequences of client's substance use;
  - (b) dangers of drinking and/or using drugs and driving;
  - (c) modifying substance use habits; and
  - (d) impact of driving under the influence on others, including victims.
- (2) When the assessment of a client under 21 years of age establishes that the client is not developmentally able to participate in programming for adults, the licensee shall provide alternative programming addressing concerns pertinent to youth. Alternative programming shall be submitted to the Department for approval at the time of application for a license or renewal. The Department shall provide its determination approving or denying the alternative programming in writing.

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(3) Special programming, either directly, through qualified service organization agreement or by referral to other programs to accommodate:

- (a) clients who do not speak English;
- (b) clients' employment, military, school and/or child care schedules; and,
- (c) clients suffering from mental health disorders, which limit their ability to participate in the licensee's group programming.

(4) Referral to community-based self help group meetings.

(D) Individual Treatment Plan: The treatment plan required by 105 CMR 164.073 Individual Treatment Plan shall be reviewed at mid-point in the group educational programming.

(E) Termination and Discharge:

- (1) Involuntary Termination: the licensee shall include in its termination policy a provision for immediately notifying the referring body of the termination of any client for failure to comply with program rules, intoxication and/or disruptive behavior.
- (2) Upon completion of the treatment program, the licensee shall conduct an exit interview, and shall make referrals available to the client to ensure a continuum of care. If the client refuses referrals, the refusal shall be documented in the client record

**164.213 Staffing Pattern**

The licensee shall establish a staffing pattern that includes the following positions in sufficient numbers to deliver required services:

- (A) a Senior Clinician responsible for the clinical/educational operation of the substance abuse service;
- (B) a Senior Clinician or Clinician to provide group education sessions.

**164.214 Fees**

The Department and the Division of Health Care Finance and Policy ("Division:") shall coordinate their respective fee and rate setting responsibilities. Pursuant to 114.3 CMR 46.00, the Division shall establish rates for service for all government purchased driver alcohol education and treatment services. The Department shall adopt the rates for services established by the Division as the schedule of fees required by M.G.L. c. 90, § 24D.

**164.215 Hours of Operation**

The licensee shall be open as necessary to provide the required services on a schedule that ensures client access to day and evening programs, including at least one group available in the evening or on weekends.

**164.221 COUNSELING:**

**164.222 Provision of Services:**

- (A) Admission: At the time of admission, the licensee shall determine that outpatient counseling services are appropriate based on:

- (1) the existence of a substance use disorder or a mental or behavioral disorder due to psychoactive substance use,
- (2) absence of withdrawal symptoms,
- (3) ability to engage and remain in treatment, and
- (4) availability of community support for recovery.

This determination shall be made during the first visit.

- (B) Assessment: The licensee shall ensure that the assessment required by 105 CMR 164.072 is completed during the first visit.

**164.223 Admission of Operating Under the Influence Second and Multiple Offenders for Aftercare Treatment Services**

When admitting individuals who have been convicted of more than one charge of operating a motor vehicle under the influence, the licensee shall comply with all requirements set forth in 105 CMR 164.222 through 164.225.

- (A) Individuals may be admitted for aftercare services following completion of a 14-day residential driving under the influence program or while awaiting placement in such a program.
- (B) Counseling services shall emphasize consequences of alcohol and/or drug use while driving.
- (C) The licensee shall provide regular reports of the client's status to the referring court or other referring agency. The licensee shall provide to the referring court or agency a complete evaluation of the client's compliance with the service plan 30 days prior to the end of one complete year of outpatient treatment. One year of outpatient treatment must follow adjudication. All such reports shall comply with 105 CMR 164.084 Confidentiality.
- (D) The licensee shall conduct alcohol and drug screening on a random basis.

**164.224 Staffing Pattern**

The licensee shall establish a staffing pattern in sufficient numbers and positions necessary for the level of care provided. Staffing pattern shall include the following positions:

- (A) A full-time equivalent Senior Clinician among direct service staff who shall be responsible for the clinical/educational operation of the substance abuse service;
- (B) Licensed psychiatrist or licensed psychologist on staff or available through a Qualified Service Organization Agreement;
- (C) Additional direct service clinical staff, as needed, to ensure service is provided through a multidisciplinary team as required by 105 CMR 164.048 (B);
- (D) Staffing in sufficient numbers to provide coverage on all shifts.

**164.225 Hours of Operation**

The program shall be open to provide services 40 hours per week. At least seven hours shall be at a time other than between 9:00 A.M. to 5:00 P.M. Monday through Friday. Satellite office shall be open to clients at least 21 hours a week and offer more than 40 staff hours a week of substance abuse treatment services to clients.

**164.231 DAY TREATMENT**

**164.232 Provision of Services**

- (A) Admission: At the time of admission, the licensee shall determine that day treatment services are appropriate for the client based on:
- (1) the client's substance use disorder;
  - (2) absence of withdrawal risk; and
  - (3) presence of substantial relapse risk and need for a structured program in order to engage and remain in treatment. This determination shall be made during the first visit.
- (B) Assessment: The licensee shall ensure that the assessment required by 105 CMR 164.072 shall be completed during the first visit.
- (C) Treatment: The licensee shall provide each client with:
- (1) Three and one-half hours of services each day, five days per week. Such service program shall meet the requirements of 105 CMR 164.074 Minimum Treatment Service Requirements and also include counseling, psychoeducational groups, and family counseling; and,
  - (2) Case management services including referrals to other services and supports to ensure a continuum of care for the client, encouragement of client use of self-help groups or other sources of community support for recovery, and aftercare service planning.

**164.233 Staffing Pattern**

The licensee shall establish a staffing pattern that includes the following:

- (A) A full-time equivalent Senior Clinician among direct service staff who shall be responsible for the clinical/educational operation of the substance abuse service;
- (B) Licensed psychiatrist or licensed psychologist on staff or available through a Qualified Service Organization Agreement;
- (C) Additional direct service clinical staff, as needed, to ensure service is provided through a multidisciplinary team as required by 105 CMR 164.048 (B);
- (D) Staffing in sufficient numbers to provide coverage on all shifts.

**164.234 Hours of Operation**

Day treatment programs shall be open to provide services a minimum of five days per week, at least three and one-half hours per day.

**164.300 OPIOID TREATMENT**

Opioid treatment is an organized, ambulatory, addiction treatment program for opiate addicted persons, providing opioid agonist treatment medication and counseling and other services needed to assist the client in achieving stability. Opioid treatment includes both maintenance and detoxification.

**164.301 Scope**

Provisions of 105 CMR 164.302 through 164.317 apply to all opioid treatment programs. The licensee shall also comply with all provisions of Part One of these regulations.

**164.302 Provision of Services – All Opioid Treatment Programs**

**(A) Admission:**

- (1) **Level of Care:** Prior to admitting a client into treatment, the licensee shall determine that the client has a current physiologic dependence on opioids of at least a 12-month duration. If the exact term of physiologic dependence cannot be determined, the medical director, or designee, may admit the client to treatment if there is sufficient evidence to reasonably conclude that there was physiologic dependence one year prior to admission. The 12-month duration may be waived if the client:
  - (a) is pregnant;
  - (b) is seeking opioid detoxification services;
  - (c) has been released from a penal institution within the previous 6 months; or
  - (d) has been discharged from opioid treatment within the previous 2 years.
- (2) **Evidence of Physiologic Opioid Dependence:** The licensee shall obtain evidence of physiologic dependence on opioids through reliable methods such as physical examination, laboratory tests and substance use history.
- (3) **Prior to initiating treatment, the licensee shall:**
  - (a) verify that the client with a positive drug screen for methadone is not enrolled in another opioid treatment program;
  - (b) complete an assessment of patient's current prescription medications in relation to interactions with opioid agonist medications, which may be prescribed in the course of treatment. Prior to prescribing, dispensing or administering an approved opioid agonist medication, the licensee shall ensure that the approved medication is not contraindicated by the patient's current prescribed medications or health status; and
  - (c) for women of child bearing age, complete a pregnancy test before dispensing or administering an approved opioid agonist medication.
- (4) **Consent to Treatment:** The licensee shall ensure that the client voluntarily chooses treatment. The information listed below shall be provided to the client and recorded on a consent form, which shall be signed by the client, and a copy shall be provided to the client. If the client is under the age of 18, the consent form shall be signed by the client and the client's parent or guardian. The information shall also be provided orally:
  - (a) the nature of opioid agonist medications used in opioid treatment, including benefits and risks;
  - (b) the distinction between detoxification and maintenance and the availability of short-term detoxification treatment for a period not less than 30 days nor more than 180 days;



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- (c) approximate length of each type of treatment;
- (d) a clear statement of the goals of each type of treatment, and the tasks necessary to reach those goals;
- (e) need for the client to inform the licensee of current medical conditions and medications the client is currently taking;
- (f) acknowledgement that the client may withdraw voluntarily from treatment and discontinue use of medications;
- (g) the options available to both the client and the program as a result of either a voluntary or involuntary termination, including medically supervised withdrawal; and
- (h) for women of child bearing age, acknowledgement of the benefits and risks of treatment during pregnancy, and importance of informing the licensee if she is or becomes pregnant.

(B) **Assessment:** The licensee shall ensure that the assessment required by 105 CMR 164.072 shall be completed on the first visit.

(C) **Physical Examination:** The licensee shall ensure that each client has a physical examination by a physician, or by a qualified health-care professional under the supervision of a program physician prior to administration of the first dose of medication. The examination shall include:

- (1) an assessment of the patient's substance use disorder;
- (2) a brief mental status exam;
- (3) tests for the presence of opiates, alcohol, benzodiazepines, cocaine and other drugs of abuse as indicated by the patient's current substance use;
- (4) an assessment of the possibility of: infectious diseases, including HIV, TB, Viral Hepatitis and sexually transmitted diseases; pulmonary, liver, and cardiac abnormalities; dermatological and neurological sequelae of addiction; and possible concurrent surgical problems. The assessment shall include the following laboratory tests, results of which must be returned no later than 14 days after admission:
  - (a) tests to determine liver function;
  - (b) tests to screen for anemia, coronary risk factors; and
  - (c) complete blood count and differential blood tests.

The licensee shall ensure that such laboratory tests are completed by licensed facilities which comply with all applicable federal and state laboratory licensure and certification requirements.

(D) **Treatment Plan:** In addition to the requirements of 105 CMR 164.073 Individual Treatment Plan, the treatment plan shall include the following information:

- (1) **Dosage:** The Medical Director shall ensure that the initial dose of an opioid agonist treatment medication is ordered by a program physician and does not exceed the federal dosage guidelines for the specified opioid; and
- (2) **Services:** The licensee shall provide services as specified in 105 CMR 164.074 Minimum Treatment Service Requirements.

(E) **Documentation:** In addition to the requirements of 105 CMR 164.083 Client Records, the medical director, or other authorized staff physician, shall:

- (1) ensure that evidence of current physiological dependence is entered in the client record;
- (2) ensure that a medical evaluation, including a medical history, is recorded;
- (3) ensure that appropriate laboratory results are documented;

- (4) ensure that a list of prescription medication, prescribed dosage(s) of all medications, the plan for changing prescribed medications if necessary, including the planned rate of detoxification, when applicable, are documented in the record;
- (5) sign or countersign all medical orders;
- (6) review and countersign treatment plans at least annually; ;
- (7) ensure that the reasons for any changes in dosage and changes in the permitted number of take-home doses are documented; and
- (8) document program verifications made in accordance with 164.302 (A)(3)(a).

(F) Identification: The licensee shall have a photographic or biometric identification system for identifying clients when dispensing opioid agonist treatment medications.

**164.303 Additional Service Requirements for Opioid Detoxification**

(A) Admission: The licensee shall apply the following additional criteria in admitting clients to opioid detoxification services:

- (1) Prior to admitting an individual for opioid detoxification, the licensee shall obtain and include in the client's record a medical evaluation by a licensed physician, psychiatrist, nurse practitioner or physician assistant which confirms the appropriateness of outpatient detoxification for the client.
- (2) Persons under 18 years of age may be admitted upon determination by the medical director to be currently physiologically dependent upon opioids as defined in 105 CMR 164.302(A)(2).
- (3) Clients with two or more unsuccessful episodes of supervised withdrawal within the previous 12 months may not be admitted to opioid detoxification treatment. The medical director shall conduct an assessment to determine an appropriate referral to another form of treatment.
- (4) A waiting period of at least one week is required between detoxification attempts. An authorized staff physician shall document in the client record that the client continues to be or is again physiologically dependent on an opioid drug.

(B) Treatment: The licensee shall ensure the following provisions are met:

- (1) The medical director shall determine for each client the rate at which the opioid drug is to be decreased;
- (2) At least one drug screening shall be performed upon admission to opioid detoxification. If the detoxification period exceeds 30 days, the licensee shall obtain at least one drug screen per month for the duration of detoxification;
- (3) Treatment plans shall be reviewed with the client monthly;
- (4) The licensee shall dispense opioid agonist treatment medications to the client daily at the facility under the direct supervision of a physician or other qualified medical person; and
- (5) The licensee shall not provide take-home medication for detoxification.

**164.304 Additional Service Requirements for Opioid Maintenance**

(A) Admission of Persons under 18 years of age: Licensees may not admit a person under 18 years of age to opioid maintenance treatment unless that person has two documented unsuccessful

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attempts at short-term detoxification or drug-free treatment within the previous 12 months, or is pregnant.

**(B) Drug Screening: The licensee shall provide for the following:**

- (1) An initial drug-screening completed for each prospective client as required by 105 CMR 164.302(C)(3) above.**
- (2) At least fifteen additional random drug screens for opioid agonist, opiates, cocaine and benzodiazepines for each client during each year in treatment. In addition, the Commissioner, as necessary to protect the health and safety of individuals in Opioid Treatment Programs, may authorize the addition of a drug to the testing regimen, state-wide or in a particular region of the state, based on changes in identified drug use. Such requirements shall not exceed a period of twelve months without amendment to these regulations. Licensees may provide 24 hour notice when urine testing is used. For all other testing methods, no prior notice shall be given. The licensee shall document measures taken to prevent adulteration of samples and to ensure a chain of custody.**
- (3) Results of drug screening are to be used as a clinical tool and not as the sole factor in the diagnosis and treatment of the client and for monitoring the client's drug-use patterns before and during treatment. The licensee's Medical Director shall ensure that drug screen results are not used to force a client out of treatment, but are used as an aid in making treatment decisions.**
- (4) Drug screening may be done by one of the following: blood, oral swab, urine testing, or other method as defined by the Department.**

**(C) Administration of Opioid Maintenance: The licensee shall provide for the following**

- (1) All clients who begin opioid maintenance treatment shall present themselves daily for medication so that the licensee may observe the client ingesting the prescribed dosage of opioid agonist medication on a daily basis.**
- (2) The licensee may reduce the number of times clients must present themselves for observed ingestion of medication by providing take-home doses. In determining whether to provide take-home doses, the licensee shall assess the client's status based on the following criteria:**
  - (a) absence of recent abuse of drugs, including alcohol;**
  - (b) regularity of program participation;**
  - (c) absence of serious behavioral problems at the program;**
  - (d) absence of recent criminal activity;**
  - (e) stability of client's home environment and social relationships;**
  - (f) length of time the client has participated in comprehensive maintenance treatment;**
  - (g) assurance that the take-home medication is safely stored within the client's home;**
  - (h) whether the benefit derived by the client from decreasing program contact outweighs the potential risks of diversion.**

The results of such assessment shall be documented in the client's record.

**(3) The licensee shall adhere to the following limits in providing take-home doses:**

- (a) During the first two months of treatment no take-home doses shall be permitted;**
- (b) Beginning in the third month of treatment, the licensee may provide one take-home dose per week.**

- (c) During the fourth through sixth months of treatment, the licensee may provide up to two take-home doses per week.
  - (d) During the seventh through ninth months of treatment, the licensee may provide up to three take-home doses per week.
  - (e) Beginning in the tenth month of treatment, the licensee may provide up to six take-home doses per week.
  - (f) Following completion of eighteen months of treatment, the licensee may provide up to thirteen take-home doses every two weeks.
- (4) The licensee may not exceed the above limits without written permission from the Department. Requests for such permission shall be submitted to the Department in writing in a form required by the State Methadone Authority and, where required, by the federal government.
- (5) Take-home doses shall be dispensed to clients in locked containers. Licensees may require clients to provide their own locked container.
- (6) Licensees shall instruct clients receiving take-home doses, including clients receiving a single take-home dose due to severe weather, of the dangers of ingesting methadone to children, pets, and others for whom methadone is not prescribed, and of the dangers of ingesting more than the prescribed dose. Such instruction shall include information on safe storage of methadone in the home. The licensee shall document that this instruction has been provided.
- (7) Take-home privileges may be revoked or suspended if the client does not maintain the behavior which supported approval of take-home privileges. Suspension or revocation of take-home privileges are not subject to appeal to the Department.
- (D) Pregnant Women
- (1) Pregnant women, regardless of age, who have had a documented opioid dependency in the past and who may be in direct jeopardy of returning to opioid dependency may be placed on a maintenance regimen. For such clients, evidence of current physiological dependence on opioid drugs is not needed if an authorized staff physician, certifies the pregnancy and, using reasonable clinical judgment, finds such treatment to be medically justified in accordance with best medical practices considering the health of the woman and impact on the pregnancy. Evidence of all findings shall be recorded in the client record.
  - (2) The licensee shall ensure that each pregnant woman is fully informed concerning the possible benefits and risks of opioid treatment to herself and to the fetus. The licensee shall document provision of this information in the client's record.
  - (3) The licensee shall establish a qualified service organization agreement for pre-natal, obstetrical and gynecological services, unless licensee provides these services directly.
- (E) Blind Dosage Reduction: Clients who are undergoing medically supervised withdrawal as a planned goal in a maintenance program may request a blind dosage reduction, i.e. a gradual decrease of dosage without prior notice to the client of the decrease. Such blind dosage reduction shall be undertaken only with written consent of the client and licensee. Such consents shall be renewed only by mutual agreement on a regular basis.
- (F) Voluntary Termination: Upon request of a client, or when deemed medically advisable and with the client's consent, the licensee shall initiate the following services:
- (1) Discuss with the client the benefits and risks of medically supervised withdrawal, including possibility of relapse;

- (2) Provide relapse prevention services;
- (3) Provide medically supervised withdrawal services directly or by referral; and
- (4) Make referrals as necessary to ensure a continuum of care for the client, including continued counseling and other services, including risk reduction and outreach, as long as necessary to assure stability.

(G) **Medically Supervised Withdrawal Rate:** The rate of medically supervised withdrawal shall be determined by the licensee's medical director to be appropriate to the client's medical and psychiatric conditions and the dosage level at which the client was being medicated before the decision was made to terminate. In determining the appropriate course of dosage reduction, the medical director shall review the client's record, and consider the client's physical and mental health status, and with consent of the client, may take into account the opinions of the client's other physicians and medical providers.

**164.305 Report of Adverse Reactions**

Within 14 days of any adverse physical or psychological reaction to an opioid agonist medication, the licensee shall report this reaction to the Food and Drug Administration (FDA) in the form and manner required by the FDA.

**164.306 Referral to Medication Unit**

In referring clients to a medication unit, the licensee shall ensure that:

- (A) Medication unit is staffed and equipped to assess clients' dosage levels;
- (B) Clients continue to receive medical and rehabilitative services as described in their treatment plans.

**164.307 Drug Screening Policy and Procedure**

The licensee shall provide for testing and analysis for drugs of abuse, and shall establish written policies and procedures for guarding against adulteration of such tests.

**164.308 Diversion Control**

The licensee shall maintain a diversion control plan which includes:

- (A) Measures to reduce the possibility of diversion of controlled substance from use for legitimate treatment; such measures shall include random callbacks for clients receiving the maximum allowable take-home doses;
- (B) For clients who test positive for methadone at admission, procedures for determining whether clients are enrolled in other opioid treatment programs, and documentation of actions taken in client records; and
- (C) Assignment of specific responsibility to the medical director and administrator for carrying out the diversion control measures and functions described in the plan.

**164.309 Involuntary Termination from an Opioid Treatment Program**

(A) **Emergency Terminations:** the licensee may terminate a client immediately prior to a hearing and without provision for medically supervised withdrawal, under the conditions listed below:

- (1) when the program director reasonably determines that the client's continuance in the program presents an immediate and substantial threat of physical harm to other clients, program personnel or property; or
- (2) where the program's Medical Director reasonably determines that continued treatment of a client presents a serious documented medical risk; and
- (3) the licensee immediately notifies the client of the decision and the reasons for the decision to immediately terminate the client;
- (4) the licensee schedules a hearing, to be held on the next business day, on the decision to terminate, and provides notice of the hearing to the client as described in 105 CMR 164.309(B)(1)(a)(i) and (iii) and (C);
- (5) the hearing is conducted in accordance with procedures specified in 105 CMR 164.309 (D) Hearing Procedures providing that the decision required by 105 CMR 164.309 (D) (7) shall be made within one business day;
- (6) the client is notified of findings of the hearing within one business day of the hearing;
- (7) the licensee provides referrals to ensure a continuum of care for the client, including continued counseling and other services, including risk reduction and outreach.

Licensees are not required to provide medically supervised withdrawal services to clients who are discharged on an emergency, involuntary basis.

(B) **Non-Emergency Termination:** In a non-emergency situation, the licensee must afford the client the following procedural rights:

(1) Prior to initiating medically supervised withdrawal, the licensee shall:

(a) Provide the client with prompt written notice which shall contain:

- (i) a statement of the reasons for the proposed termination, e.g. violations of a specific rule or rules, non-compliance with treatment contract, etc., and the particulars of the infraction including the date, time, and place;
- (ii) notification that the client has the right, within two business days from the first business day following receipt of written notice, to submit a written request for a hearing as to the proposed termination;
- (iii) a copy of the licensee's hearing procedures.

(b) Arrange with the client or client's advocate for a mutually convenient date and time for a hearing within ten business days of receipt of the notice. Additional time to secure appropriate representation may be granted to the client under exceptional circumstances.

(2) Afford the client the opportunity of medically supervised withdrawal. If the client chooses medically supervised withdrawal, the licensee shall provide medically supervised withdrawal, or make arrangements for appropriate medically supervised withdrawal in another opioid treatment program. The rate of dosage reduction shall be determined by the licensee's medical director in accordance with the client's medical condition and the dosage level at which the client was medicated before the decision was made to terminate or suspend. In determining an appropriate course of withdrawal, the medical director shall review the record, consider the client's physical and mental health status, and, upon request of the client, may take into account the opinions of the client's other physicians and medical providers.

- (3) If a client is terminated for non-payment of fees, medically supervised withdrawal may begin immediately upon providing written notice of termination, and continue concurrent with client's appeal, if any.
- (C) Documentation of Receipt of Notice: The licensee shall document provision of notice to the client by obtaining the signature of the staff person providing notice and by obtaining a signed, dated receipt from the client. If the client refuses to sign a receipt, the licensee shall document that refusal on its record of notice.
- (D) Hearing Procedures: The licensee shall ensure that hearings are conducted in accordance with the following procedures:
- (1) The hearing shall be presided over by an impartial hearing officer, who may be any staff or other person(s) not directly involved in the facts of the incident giving rise to the disciplinary proceedings or in the decision to commence the proceedings; provided that the persons involved in either the facts of the incident or in the decision to commence the proceedings shall not have authority over the hearing officer(s);
  - (2) The client may be represented at the hearing by any responsible adult of the client's choosing, including legal counsel;
  - (3) The hearing shall be conducted in accordance with previously established written rules, which need not be the rules of evidence used in judicial proceedings, but which are designed to ensure a fair and impartial proceeding. The program shall prove by a preponderance of the evidence that the client did commit the alleged violation;
  - (4) The client shall be entitled, upon request, to examine any documentary evidence in the possession of the licensee that pertains to the subject matter of the hearing;
  - (5) The client shall be entitled to call his/her own witnesses and to question any adverse witnesses;
  - (6) The licensee shall make an audio recording of the hearing. The client may also make an audio recording of the hearing at the client's expense;
  - (7) The hearing officer shall make the decision within seven business days after the hearing and will base the decision solely upon the information presented at the hearing. The decision shall be based upon the licensee's policy and procedures in effect and posted at the time of the violation; and
  - (8) The hearing officer shall issue the decision in writing, and shall provide the client (and client's representative, if requested) with a copy thereof. The decision shall include an explanation of the reasons for the decision, and instructions explaining how to file an appeal of an adverse decision to the Bureau. The instructions shall inform the client that the client's written request for an appeal constitutes the client's consent to release information to the Bureau.

**164.310 Bureau Review of Program Decisions to Terminate**

- (A) The licensee shall afford the client the right to appeal to the Bureau an adverse decision of the hearing officer. The client must request this appeal in writing to the Bureau within three business days following the receipt of the adverse decision. The client's written appeal shall contain the client's argument in support of the appeal. The Bureau will either affirm or reverse the hearing officer's decision, or remand the decision to a new hearing officer for a new hearing. The decision of the Bureau will be made as follows:
- (1) In the case of an emergency termination, the Bureau shall decide within one business day of receipt of the complete hearing record and written materials submitted by both parties;
  - (2) In the case of a non-emergency termination, the Bureau shall decide within ten business days of the Bureau's receipt of the complete hearing record and written materials submitted by both parties.

A licensee's failure to submit the complete hearing record will result in a finding for the client. The hearing officer shall deliver a written decision, outlining the reason(s) for the decision, to the client, his/her advocate, and the program. The decision of the Bureau is final.

- (B) In the case of a non-emergency termination, if the client timely appeals the hearing decision, the licensee may not terminate the client or begin medically supervised withdrawal without first receiving, and ensuring that the client also receives, the Bureau's decision on appeal.

**164.311 Authority to Operate an Opioid Treatment Program**

- (A) Compliance with Other Laws, Rules, Regulations and Standards: In addition to these regulations, the licensee shall comply with the following:
- (1) M.G.L. c. 94C governing controlled substances and 105 CMR 700.00 et seq. Implementation of M.G.L. c. 94C governing controlled substance registration;
  - (2) 21 CFR Parts 1300 to 1399 of the U.S. Department of Justice, Drug Enforcement Administration (DEA) regulations requiring registration under the Controlled Substances Act.
- (B) Current Certification: The licensee shall have a current valid certificate from the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services, in compliance with 42 CFR Part 8.
- (C) Accreditation: The licensee shall be accredited by an accrediting organization approved by the Substance Abuse and Mental Health Service Administration. If the licensee has operated an opioid treatment program for less than one year, the licensee shall obtain accreditation by the end of the first year of operation.
- (D) State Authority Approval: No person, agency or entity may operate an opioid treatment program in the Commonwealth of Massachusetts without State Authority Approval, except for opioid treatment programs operated by the Veterans Administration or programs directly operated by the federal government. Persons who hold a current license and State Authority Approval to operate an opioid treatment program may not open a new or relocated facility, or transfer ownership, without applying for and receiving a new license and State Authority Approval.
- (1) Application for State Authority Approval: Applicants for State Authority Approval shall submit a completed "Request for State Authority Approval to Operate an Opioid Treatment Program" in conjunction with an application for licensure pursuant to Part One of these regulations. Copies of the Request for State Authority Approval shall be submitted to the United States Substance Abuse and Mental Health Services Administration and the United States Drug Enforcement Administration. In addition to information and inspections required for licensure, the application shall specify:
    - (a) the number of active clients to be served at the site(s); and
    - (b) security protocols.
  - (2) Approval Process:
    - (a) If the Department determines that the applicant has met all state and federal standards and that the interests of public health would be served by the establishment of the opioid treatment program, the Department shall forward State Authority Approval to the Substance Abuse and Mental Health Services Agency (SAMHSA).
    - (b) Upon State Authority Approval, the Department shall issue a provisional license valid for six months and shall sign and forward it to the SAMHSA.



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- (c) The Department may review the program's operations during the provisional licensing period. Following the provisional period, the Department shall make a recommendation regarding the issuance of a two-year license.
- (d) If the Department determines that the applicant has not met the requirements of state and federal regulations and/or that the interests of public health are not served by the establishment of the opioid treatment program at the proposed site, the Department shall deny State Authority Approval of the application in writing, citing specific reasons for denial, and forward its denial to the SAMHSA. If denied, the applicant may request an adjudicatory hearing, pursuant to M.G.L. c. 30A and 801 CMR 1.01(7).
- (e) The State Authority may make a request to SAMHSA to revoke SAMHSA approval of a opioid treatment program for cause.

**164.312 Inspections**

In addition to inspections specified in 105 CMR 164.011 Inspections and 164.310 Authority to Operate an Opioid Treatment Program, the licensee shall permit the following inspections:

- (A) The licensee shall allow inspections by duly authorized employees of the State Authority, Drug Enforcement Agency, and SAMHSA at any time.
- (B) A hospital or Department of Mental Health licensed facility subject to 105 CMR 164.012 shall permit the State Authority and Drug Enforcement Agency to inspect supplies of opioid drugs for opioid addiction treatment which are located at the hospital or facility at any time and to evaluate how the drug(s) are being used. In addition, records on receipt, storage, and distribution of opioid medication are subject to inspection.

**164.313 Required Notifications**

Licensees shall notify the Department of the following:

- (A) Change in Program Sponsor or Medical Director. The opioid treatment program must provide written notice to the State Authority of a replacement of a program sponsor or Medical Director within two weeks of any replacement of these personnel.
- (B) Closure or Cessation of Operation. The opioid treatment program must provide written notice to the State Authority 90 days in advance of discontinuing a program in which medication is administered or dispensed. In addition to requirements of 105 CMR 164.035 (C) and 105 CMR 164.087 Closure, the licensee shall include in its notice its plan for storage, transfer or disposal of its supply of opioids. Such plan shall be subject to approval by the Department.

**164.314 Staffing Pattern**

- (A) The licensee shall designate as medical director a physician who shall be responsible for administering all medical services provided by the program. The Medical Director shall have six months' clinical experience with alcohol and other drug-dependent persons or 40 hours of documented continuing education in treating addicted persons within the first twelve months of employment. The Medical Director shall be responsible for:
  - (1) Ensuring that a medical evaluation, including a medical history is taken for each client;
  - (2) Ensuring that appropriate laboratory studies are completed and recorded in client records; and
  - (3) Signing all medical orders.
- (B) The licensee shall establish a staffing pattern in sufficient numbers and positions necessary for the level of care provided. Staffing pattern shall include the following positions:

- (1) Senior Clinician among direct service staff who shall be responsible for the clinical/educational operation of the substance abuse service;
  - (2) Licensed psychiatrist or licensed psychologist on staff or available through a Qualified Service Organization Agreement;
  - (3) Registered nurse, nurse practitioner, physician assistant or licensed practical nurse on staff and on site during hours when medication is dispensed;
  - (4) If serving pregnant women, an obstetrician/gynecologist available on staff or through a Qualified Service Organization Agreement;
  - (5) Sufficient staff to ensure coverage on all shifts.
- (C) Supervision: In addition to supervision requirements set forth in 105 CMR 164.044 Training and Supervision, the licensee shall ensure that supervision of nursing staff is overseen by a registered nurse.

**164.315           Hours of Operation**

The program shall be open to provide treatment and to administer medications seven days per week, year round. Consideration should be given to the employment, homemaking, and educational needs of the clients. Services provided on at least five of the seven days shall be on the basis of an eight-hour day, provided that a minimum of two of the eight hours are scheduled other than 9:00 A.M. to 5:00 P.M. Medication dispensing during the remaining two days must be scheduled for a period of at least two hours.

**164.316           Severe Weather Accommodation**

- (A) The licensee shall establish written policy and procedures for ensuring continued dispensing of medications in the event of severe weather conditions such as hurricanes or blizzards. The policy shall be approved by both the Executive Director and Medical Director, and shall include the following:
- (1) Method for notifying clients of the licensee's plan for ensuring continued availability of medications;
  - (2) Provision of no more than one additional take-home dose to clients who are already receiving take-home doses;
  - (3) Provision of no more than one take-home dose to clients not currently receiving take-home doses;
  - (4) Method for ensuring clients who receive take-home doses in accordance with (A)(3) above are capable of taking medication according to prescribed instructions;
  - (5) Provisions for ensuring continuity for clients who are receiving doses at home;
  - (6) Criteria for applying provisions listed in 105 CMR 164.304 (C) (2) regarding take-home doses; and
  - (7) Provisions for applying safeguards described in 105 CMR 164.304(C)(6).
- (B) Licensees shall document compliance with the requirements of (A) (1) through (7) in client records.
- (C) Clients not currently receiving take-home doses who receive one dose in accordance with this section are not required to provide a locked container.
- (D) Licensees shall document compliance with 42 CFR Part 8: Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction.

**164.317           Required Affiliations**

The licensee shall establish and maintain Qualified Service Organization Agreements with facilities licensed to provide emergency inpatient medical and psychiatric services.

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**164.400 RESIDENTIAL REHABILITATION**

Residential rehabilitation services are organized substance abuse treatment and education services featuring a planned program of care in a 24-hour residential setting. Services are provided in permanent facilities where clients reside on a temporary basis. They are staffed 24 hours a day. Residential rehabilitation services are provided to clients who require safe and stable living environments in order to develop their recovery skills. Types of residential rehabilitation services are those designed for: adult individuals, adults with their families, adolescents, and driving under the influence second offenders.

**164.401 Scope**

Provisions of 105 CMR 164.402 through 164.409 apply to all residential rehabilitation substance abuse treatment services. Licensees shall also comply with all provisions of Part One of these regulations.

**164.402 Hours of Operation**

Residential rehabilitation services shall operate 24 hours a day, seven days a week, 365 days a year.

**164.403 Prohibition of Alcohol or Drugs**

Licensees shall ensure that alcohol and drugs, other than those properly prescribed by a resident's physician, are prohibited on the premises.

**164.404 Physical Plant**

(A) Inspections: The licensee shall post in public areas certificates confirming that all local inspections required for operation of the facility are up to date.

(B) Compliance with Building Standards: The licensee shall ensure that:

- (1) The facility complies with standards specified in 105 CMR 410 Standards of Fitness for Human Habitation regarding heating, electricity, lighting, plumbing and sanitary facilities; and
- (2) The heating system conforms with requirements defined by the Department of Public Safety (520 CMR, 522 CMR, and 527 CMR) under M.G.L. c. 148.

(C) Location: The licensee shall ensure that residential rehabilitation facilities meet the following requirements:

- (1) The licensee shall not post signs or notices that would identify the building as a residential rehabilitation facility, except that programs located in large campuses or health care complexes may post signs to provide direction.
- (2) If the residential facility is located in another facility such as a hospital or nursing home, the area to be used for the residential facility shall be clearly differentiated. A licensee proposing to locate a residential facility in a portion of a larger health care facility shall seek a determination from the Division of Health Care Quality that the location of the residential recovery program in that facility does not jeopardize the status of that facility for purposes of state licensure or federal Medicare or Medicaid certification.

(D) Common Areas: Licensees shall design and furnish residential facilities in a manner consistent with their use and which provides a homelike setting including:

- (1) space for group counseling area that insures privacy and that is large enough to accommodate the number of adult residents in the facility;
- (2) space for residents to use for recreation, reading and quiet time;
- (3) laundry facilities;
- (4) closets, cabinets, or other closed spaces for storage of residents' belongings;
- (5) nightlights in corridors and bathrooms; and
- (6) in programs where children reside, a separate indoor play area for children, which includes closets or cabinets for storage of play material, and an outdoor play area.

None of the areas listed in (1) through (4) and (6) above may be used as bedrooms.

**(E) Bathrooms and Personal Hygiene:** The licensee shall ensure that:

- (1) Female and male residents have separate toilet and bathroom facilities;
- (2) All rooms containing toilets, bathtubs and/or showers are equipped with a door, and have ventilation to the outside through a window or extractor vent;
- (3) No room containing a toilet or shower is so located as to require passing through to go from one area of the premises to another;
- (4) There is at least one toilet for every eight women (1:8) and one toilet for every ten men (1:10), and one washbasin and one shower or tub for each ten residents (1:10), excluding infants;
- (5) Washbasins are located in the same room as or in close proximity to toilets;
- (6) All showers and tubs are equipped with a non-slip surface or mat;
- (7) All toilets have seats;
- (8) Sanitary hand washing requirements and procedures are posted in restrooms and diapering areas, and licensee familiarizes staff and families with these procedures;
- (9) Staff and residents use disposable gloves during toileting and diaper changing of children, and dispose of soiled diapers and gloves in a container with a secure lid;
- (10) Restrooms are maintained in good repair and a sanitary manner, cleaned daily, and supplied with sufficient soap, paper towels and toilet paper at all times.

**(F) Sleeping Rooms:**

- (1) All sleeping rooms shall be near toilet, lavatory, and bathing facilities.
- (2) Female and male adult residents shall have separate sleeping quarters. Licensees may permit couples to share sleeping quarters if space permits.
- (3) Sleeping areas shall be designed to promote comfort and provide adequate space and privacy for residents; and shall meet the following requirements:
  - (a) No sleeping room shall be less than 70 square feet;
  - (b) Rooms accommodating more than one person shall have a minimum of fifty (50) square feet per person, except that thirty-five (35) square feet shall be provided per child for children under six;
  - (c) No more than six persons and no more than one family per room;
  - (d) Rooms have direct windows or skylights providing natural light and ventilation in compliance with 105 CMR 410.250 and 410.280;
  - (e) A separate bed for each resident;
  - (f) A crib for each child age 2 or under;
  - (g) May not be an unfinished attic, stairway, hall or room commonly used for other purposes.
- (4) The licensee shall ensure that pillows are not used in cribs;
- (5) The licensee shall provide the following basic equipment and supplies:
  - (a) a twin size bed with a twin mattress and waterproof mattress cover; cots may not be used;
  - (b) adequate drawer and closet space for storage of personal belongings;
  - (c) an adequate supply of bed linens, pillows, blankets, washcloths and towels in good condition. Linens, blankets, washcloths and towels shall be laundered at least once a week;
  - (f) a toothbrush, toothpaste and basic hygiene materials.

- (6) Residents shall be permitted to decorate their sleeping areas with their personal possessions, such as pictures and posters consistent with the rules and philosophy of the program.

**164.405 Meals and Food Handling**

- (A) Food Storage: The licensee shall have a written plan for protecting food from contamination and spoilage during its storage, preparation, distribution and service. The plan shall provide for:
- (1) Procuring all food only from sources that ensure that the food is processed under regulated quality and sanitation controls;
  - (2) Clearly labeling supplies;
  - (3) Storing all non-food supplies in an area separate from that used for storing food supplies;
  - (4) Storing perishable foods in refrigerators at 41°F or less;
  - (5) Ensuring that any walk-in refrigerators or freezers can be opened from the inside even if closed; if the licensee padlocks walk-in refrigerators or freezers, the licensee shall establish a procedure requiring written documentation that no one is in the refrigerator or freezer prior to securing the lock.
  - (6) Frozen foods remaining frozen.
- (B) Food Handling: Persons, whether employees or residents, responsible for food preparation and service shall be free of signs and symptoms of infections, communicable diseases and open skin lesions. The licensee shall ensure that there are
- (1) Disposable gloves available and used in handling and preparing food;
  - (2) Adequate hand washing and drying facilities located close to the food preparation area; and
  - (3) All work surfaces, utensils, equipment and dishes are thoroughly cleaned and sanitized after each use.
- (C) Kitchen Facilities: The licensee shall ensure that:
- (1) The kitchen is located in a suitable area of the facility and provides adequate work space for the sanitary preparation and serving of all meals.
  - (2) Adequate sanitary storage space is provided for the proper storage of all foods, dishes, silverware and cooking equipment.
  - (3) If any resident has a food allergy, information concerning the allergy and required responses in the event of an allergic reaction are conspicuously posted in the kitchen and dining areas with permission of the resident or, if a child, of the child's parents. Licensees shall document refusal to give permission in the resident's record.
- (D) Waste Disposal: The licensee shall provide for the sanitary disposal of all waste materials in watertight trash bins with tight fitting lids.
- (E) Meals: The licensee shall provide a nourishing well-balanced diet to all residents, and shall provide for the following:
- (1) Clean, well lighted, and ventilated dining areas;
  - (2) The dining room shall be large enough so that all residents may take their meals at customary times, but not necessarily simultaneously;
  - (3) Three meals each day for residents who are not working and at least two meals for working residents;
  - (4) Beverages and food for snacks;
  - (5) Consideration of residents' suggestions for menu planning;
  - (6) Menus dated and retained for three months;
  - (7) Means to provide for residents with special dietary needs;

- (8) The licensee providing Residential Rehabilitation other than Transitional Support Services may assign program residents to prepare and serve meals as part of their household duties under the supervision of a staff member who has documented training in sanitary food handling and preparation. Residents of Transitional Support Service programs may not prepare or serve food and
  - (9) Where applicable, licensees shall ensure that food storage and preparation areas meet the standards defined in 105 CMR 590.000: Minimum Standards for Food Establishments and that the food service is inspected and receives a food service permit by the local board of health.
- (F) Purchased Food Services: If the licensee purchases food and meal services, the licensee shall obtain copies of licenses and inspections which document that the food and meal service provider conforms to 105 CMR 590 Sanitary Code Chapter X – Minimum Standards for Food Establishments.

**164.406 Safe Storage and Administration of Medications**

- (A) Written Policy and Procedure: The licensee shall establish a written policy and procedure governing the storage and administration of residents' prescription medications, including the provisions of 105 CMR 164.406.
- (B) Medications brought by residents to the program shall be stored in a locked, secure cabinet that is separate from the facility's supply, except that residents shall retain medications required to treat acute episodes, such as asthma attacks or allergic reactions.
- (1) If injectable drugs are used, licensees shall provide containers for safe storage and proper disposal of sharps.
  - (2) Medications requiring refrigeration shall be kept in a refrigerator in the same area where other medications are stored. Medications shall not be stored in kitchen refrigerators.
  - (3) The licensee shall also establish a record of medications which remain in the possession of residents for treatment of acute episodes.
- (C) Prescription medication presented by residents shall bear a pharmacy label, which shows the date of filling, the pharmacy name and address, the filling pharmacist's initials, the serial number of the prescription, the name of the resident, the name of the prescribing practitioner, the name of the prescribed medication, directions for use and cautionary statements, if any, contained in such prescription or required by law, and if tablets or capsules, the number in the container. All over-the-counter medications shall be kept in the original containers containing the original label, which shall include the directions for use.
- (D) The licensee shall maintain documentation of all medications stored and disposed of.
- (E) Upon admission the resident shall count, in the presence of staff, the number of tablets or capsules, or the approximate amount of liquid in each prescribed medication brought by the resident. The count shall be documented.
- (F) Self-Administration of Medications: Medications shall be self-administered by the resident, unless the licensee employs qualified health care professionals authorized to administer medications. Adult residents must be able to administer their own medications, and, unless the licensee employs qualified health care professionals for this purpose, staff shall not administer medication to any resident or residents' child. Staff shall observe the resident ingesting the prescribed dose. For children under 18 residing with their parents, medication shall be administered by the child's resident parent. Medications may not be provided to any resident if other residents are in the storage or office area. The licensee may provide a supply of medications for any resident who will

be absent from the program when he or she would normally take the medication. The licensee shall maintain documentation of all administrations of medication, which shall include:

- (1) Name of resident to whom medication was provided;
- (2) Name of staff person observing the resident take the medication, or providing the needed supply;
- (3) Date and time medication was provided; and
- (4) Resident initials confirming that the medication was provided and taken.

(G) **Disposing of Medications:** The licensee shall not permit expired medications, medications left behind by residents, or unused medications to accumulate in the storage area. The licensee shall establish policy and procedures for the return of the resident's medication upon discharge and for safe disposal of medications.

(H) **Improper Use:** The licensee shall establish a policy regarding improper use of medication. Such policies

- (1) may impose sanctions on residents who do not take medications in accordance with prescribed dose and frequency; and
- (2) shall impose sanctions on residents who illegally obtain and use prescription medications.

**164.407 Resident Personal Effects and Affairs**

(A) **Written Policy and Procedure:** The licensee shall establish a written policy and procedure governing the care of resident personal belongings and support of resident personal affairs.

(B) **Safekeeping:** The licensee may allow residents to bring monies and valuables into the program, if the licensee provides for the secure, locked safekeeping of the personal property.

(C) **Right to Confiscate:** All residents shall be notified that by accepting admission they authorize the licensee to:

- (1) confiscate and dispose of any alcohol or drugs (other than those properly provided by prescription) or paraphernalia for the use of illegal drugs found in the possession of the resident;
- (2) confiscate any weapons or other articles found in the possession of the patient, which may constitute a threat to the life, health or safety of the patient, the staff or public, and to turn over any guns to the police.

The licensee shall establish a record of any items confiscated or turned over to the police.

(D) The licensee shall establish written policy and procedures governing residents' use of telephones, pagers, cell phones or other communication devices, and sending and receiving mail. The licensee may not hold mail or restrict the sending of mail. The licensee may not open residents' mail, but may require that residents open letters or packages in the presence of staff. Alcohol, drugs or weapons shall be confiscated.

**164.408 Back-Up and Transfer Agreements**

Each residential program shall have Qualified Service Organization Agreements for the provision of the following services as needed:

(A) Psychiatric consultative, diagnostic and evaluative services;



- (B) Acute in-patient medical or psychiatric hospitalization;
- (C) Emergency medical and psychiatric services;
- (D) Any specialized services that a program provides through special arrangement, purchase or contract.

**164.409**      **Death of a Resident**

The licensee shall develop procedures to be followed in the event of the death of a resident. These procedures shall conform with laws governing the report of death to local authorities, and shall include the following:

- (A) Local emergency services (911) shall be notified immediately.
- (B) The licensee shall comply with all laws concerning declaration of death and moving the deceased.
- (C) The licensee shall make reasonable efforts to notify the deceased's emergency contact. A written record of these efforts shall be included in the client's record.

**164.420 RESIDENTIAL REHABILITATION FOR ADULTS**

**164.421 Scope**

Provisions of 105 CMR 164.422 through 164.424 apply to residential rehabilitation substance abuse treatment and education services for adults in the early stages of substance abuse recovery, using the following models: Transitional Support Services, Social Model Recovery Homes, Recovery Homes, and Therapeutic Communities. Licensees shall also comply with all provisions of 105 CMR 164.400 through 164.409, and Part One of these regulations.

**164.422 Provision of Services**

- (A) Admission: Level of Care: Prior to admission, the licensee shall verify that the client is 18 years of age or older and that the residential rehabilitation services are appropriate for the client based upon a determination that the client:
- (1) has a substance use disorder or a mental or behavioral disorder due to psychoactive substance use and is not intoxicated and is not currently at risk of experiencing withdrawal;
  - (2) is mentally and physically stable and does not pose a risk to self or others;
  - (3) is open to recovery and can understand relapse;
  - (4) requires a 24-hour a day structured and supportive environment in order to maintain gains;
  - (5) lives in a home, community or social environment that is unsupportive of recovery or constitutes a risk to maintenance of abstinence;
  - (6) is capable of recognizing physical danger, including when such danger requires immediate egress from the residence, and is able to follow a prescribed procedure for egress, as demonstrated by completion of a self-preservation test.
- (B) Duration of services: Length of stay may vary depending upon the needs of the client.
- (C) Assessment: The licensee shall ensure that the assessment required by 105 CMR 164.072 shall be completed within the first week of treatment.
- (D) Treatment: The licensee shall provide treatment services as required by 105 CMR 164.074 Minimum Treatment Service Requirements, in accordance with program components specified in 105 CMR 164.423 below.
- (E) Medical Services: The licensee shall refer the client for a complete physical examination within 30 days of admission unless medical reports document a comparable examination within 12 months prior to admission. Referrals shall be documented in the client's record.
- (F) Licensees providing services to pregnant and post-partum clients and their infants shall establish Qualified Service Organization Agreements with early intervention programs to provide developmental assessments and services to infants. Licensees shall also comply with requirements of 105 CMR 164.082 Special Populations, subsection (A) governing services to pregnant clients.
- (G) Exemptions:
- (1) Residential rehabilitation programs for adults are exempt from the requirement in 105 CMR 164.072 (G) that the initial assessment be completed by Senior Clinician or Clinician.
  - (2) Residential rehabilitation programs for adults are exempt from the requirements set forth in 105 CMR 164.048 (B) Multidisciplinary Team.

- (3) **Social Model Recovery Homes** are exempt from the provisions contained in **105 CMR 164.073 Individual Treatment Plan** and **105 CMR 164.074 Minimum Treatment Requirements**, to provide individual counseling.

**164.423 Program Components**

- (A) **Residential rehabilitation programs for adults, regardless of program model, shall provide:**

- (1) daily clinical services to improve residents' ability to structure and organize the tasks of daily living and recovery, such as personal responsibility, personal appearance and punctuality; and,
- (2) advocacy and ombudsman services to support residents in obtaining needed resources and services and actively promote residents' interests.

- (B) **Transitional Support Services:** Residential rehabilitation programs based on a Transitional Support model shall provide:

- (1) four hours of nursing services available each day;
- (2) intensive case management services;
- (3) transportation services available at least twelve hours per day, seven days per week;
- (4) health monitoring, education and crisis services; and
- (5) referral and follow-up for substance abuse treatment services upon discharge.

- (C) **Social Model Recovery Homes:** Residential rehabilitation programs based on a Social Model shall provide:

- (1) individual service plans developed by residents with assistance from staff, and, if resident chooses, from other residents or volunteers. The service plan shall be developed within the first 30 days of residence;
- (2) planned program activities to stabilize and maintain the stability of the resident's substance abuse dependence symptoms and to help the resident develop and apply recovery skills; and
- (3) case management and support to promote successful involvement in regular, productive daily activity, such as work or school, and, as indicated, successful reintegration into family and community living.

- (D) **Recovery Homes:** Residential rehabilitation services based on a Recovery Home model shall provide:

- (1) planned daily clinical program activities to stabilize the resident's substance dependence symptoms and to help the resident develop and apply recovery skills;
- (2) counseling and clinical monitoring by qualified staff to promote successful involvement in regular, productive daily activity, such as work or school, and, as indicated, successful reintegration into family and community living;
- (3) a range of cognitive and motivational therapies on a group and individual basis; and
- (4) a daily schedule of services designed to develop and apply recovery skills.

- (E) **Therapeutic Communities:** Residential rehabilitation services based on a Therapeutic Community model shall provide:

- (1) daily clinical services to promote the residents' ability to develop and practice pro-social behaviors;
- (2) planned daily clinical program activities to stabilize and maintain stabilization of the resident's substance dependence symptoms and to help the resident develop and apply recovery skills;

- (3) **counseling and clinical monitoring by qualified staff to promote successful involvement in regular, productive daily activity, such as work or school, and, as indicated, successful reintegration into family and community living;**
- (4) **a range of cognitive and motivational therapies on a group and individual basis;**
- (5) **motivational enhancement and engagement strategies appropriate to the resident's stage of readiness to change;**
- (6) **planned community reinforcement designed to foster pro-social values and group living skills.**

**164.424      Staffing Pattern**

The licensee shall establish a staffing pattern in sufficient numbers and positions necessary for the level of care provided. Staffing pattern shall include the following positions:

- (A) **Coverage:** At least 1 FTE direct care staff on each shift, seven days a week, twenty-four hours a day. No staff on any shifts shall be permitted to sleep during the shift.
- (B) **Direct Care Staff:** Job descriptions shall specify that direct care staff have knowledge of and ability to promote recovery.
- (C) **Licensees providing Transitional Support Services** shall ensure that a registered nurse, nurse practitioner, physician assistant, or licensed practical nurse is available on site at least 4 hours each day and shall ensure that supervision of nursing staff is overseen by a registered nurse.
- (D) **Administrative Staff:** Each residential rehabilitation program shall have a full-time manager who is responsible for the administration and operation of the residential rehabilitation program. A full-time administrative staff, or designee on duty on the premises, shall be available to respond to emergencies at all times.

**164.430 RESIDENTIAL REHABILITATION FOR ADULTS WITH THEIR FAMILIES**

**164.431 Scope**

Provisions of 105 CMR 164.432 through 164.433 apply to residential rehabilitation substance abuse treatment services for individuals with their families. The licensee shall also comply with all provisions of 105 CMR 164.400 through 164.409, and with provisions of Part One of these regulations.

**164.432 Provision of Services**

(A) Level of Care: At the time of admission, the licensee shall determine that Family Residential Substance Abuse Treatment Services are appropriate based upon the following criteria:

- (1) The parent:
  - (a) is 18 years of age or older;
  - (b) has a substance use disorder or a mental or behavioral disorder due to psychoactive substance use and is not intoxicated and is not currently at risk of experiencing withdrawal symptoms requiring medical monitoring;
  - (c) is not currently experiencing acute symptoms of physical or mental illness, and does not pose a risk to self or others;
  - (d) is open to recovery and can understand relapse;
  - (e) requires a 24-hour a day structured and supportive environment in order to maintain gains;
  - (f) has custody of at least one child or reunification with at least one child is planned within thirty (30) days of admission, or is pregnant; and
  - (g) is capable of recognizing physical danger, including when such danger requires immediate egress from the residence, and is able to follow a prescribed procedure for egress, as demonstrated by completion of a self-preservation test.
- (2) The family is homeless and is eligible for Emergency Assistance (EA) through the Department of Transitional Assistance (DTA) as determined by DTA Local Offices pursuant to the standards of 106 CMR 309; or the family has housing resources located in a community or social environment that is unsupportive of recovery or constitutes a risk to maintenance of abstinence; and,
- (3) No intoxicated persons or persons with medical conditions requiring 24-hour a day nursing coverage shall be admitted.

(B) Assessment: Within 30 days of admission, the licensee shall complete the following:

- (1) an assessment as required in 105 CMR 164.072 for each adult family member in the program;
- (2) assessments of the physical and mental health needs of all family members in the program;
- (3) evaluations, physical examinations, immunizations, and/or consultations by qualified professionals, as indicated by the assessments required under 164.432(B) (1) and (2) above.

(C) Treatment Plan: The licensee shall develop an Individual Treatment Plan as required by 105 CMR 164.073 for each family member residing in the program. In addition to substance use disorders, the treatment plan shall address mental health disorders, trauma, domestic violence, child welfare, parent-child relationships and family life.

(D) Substance Abuse Treatment Services: In addition to the Minimum Treatment Services Requirements specified in 105 CMR 164.074, the licensee shall provide the following services for adults and adolescents:

- (1) Monthly case review or consultation meetings between the licensee's staff and any Qualified Service Organizations providing services for a family under a Qualified Service Organization Agreement; and
  - (2) Twenty-four hour a day crisis intervention services.
- (E) Mental Health Services: The licensee shall establish Qualified Service Organization Agreements with licensed Mental Health Providers in order to provide the following for adults and children:
- (1) A mental health assessment that includes a history of mental health concerns or disorders and treatment, psychosocial, family and medical history, and a psychopharmacological assessment; and,
  - (2) Individual and/or group counseling for mental health issues such as childhood or adult sexual abuse, depression, domestic violence and traumatic stress symptoms.
- (F) Parenting and Life Skills Education: The licensee shall provide, either directly or through a Qualified Service Organization Agreement, the following adult services:
- (1) Weekly, on-site parenting education and parenting skill building; and
  - (2) Counseling and clinical monitoring to promote successful involvement in regular, productive daily activity, such as work or school, and, as indicated, successful reintegration into family and community living.
- (G) Transitional Assistance and Employment: The licensee shall provide advocacy services to assist the family in applying for transitional assistance through the DTA.
- (H) Services for Children Residing in the Program: The licensee shall:
- (1) Obtain parent(s)' consent prior to referring a child for services or consulting with service providers:
    - (a) Refer children from birth to age three for a Developmental Assessment through an Early Intervention Program (EIP) certified by the Department;
    - (b) Consult with other service providers or institutions providing services to children, e.g., courts, schools, Early Intervention Program, Department of Youth Services, Department of Social Services, etc.
    - (c) Ensure that children receive medical examinations in accordance with recommended schedules of pediatric care;
    - (d) Ensure that children's immunizations are up to date in accordance with the recommendations of the Department, unless the child's parent has stated in writing that vaccinations or immunizations conflict with his or her sincere religious beliefs or if the child's physician has stated in writing that the vaccination or immunization is medically contraindicated;
  - (2) Assist parent(s) in obtaining child care services, including after school child care for school-age children;
  - (3) Assist parents in ensuring school age children are registered in and attending school; and
  - (4) Provide on-site services and activities for children who are not in community-based child care programs or in school. Such services shall be designed to promote the child's development and shall be available for children of all ages, including adolescents.
- (I) Aftercare: In addition to requirements in 105 CMR 164.076 Aftercare and 164.077 Post Discharge Aftercare, the licensee shall provide the following aftercare services:
- (1) Assistance to obtain housing, child-care, employment, continued health care and other social services that the family has received while in the program.
  - (2) Follow-up services for up to 3 months following the family's discharge; and

- (3) Referral to another family residential program through policy established by the Department if the family is discharged before completion of treatment.

**164.433 Staffing Pattern**

(A) The licensee shall establish a staffing pattern that includes the following:

- (1) a Clinical Director who is a Senior Clinician;
- (2) a Family Therapist who is a Senior Clinician with experience working with families experiencing substance use disorders;
- (3) children's services staff;
- (4) counselors to serve as Recovery Specialists;
- (5) a minimum of 1 FTE staff member on site at all times;
- (6) no on-duty staff shall be permitted to sleep during their shift.

(B) The licensee shall establish policies requiring parents to ensure that children are supervised by an adult at all times.

(C) In addition to meeting staff training and supervision requirements contained in 105 CMR 164.044 Training and Supervision, the licensee shall ensure that all staff are trained to recognize child abuse and neglect and to report incidents of child abuse and neglect to the Department of Social Service under M.G.L. c. 119, § 51A.

**164.440 RESIDENTIAL REHABILITATION FOR ADOLESCENTS**

**164.441 Scope**

Provisions of 105 CMR 164.442 through 164.447 apply to residential rehabilitation substance abuse treatment services for adolescents. The licensee shall also comply with all provisions of 105 CMR 164.400 through 164.409, and with provisions of Part One of these regulations.

**164.442 Provision of Services**

(A) Admission: Level of Care: Prior to admission, the licensee shall determine that adolescent residential rehabilitation services are appropriate based upon the following criteria:

- (1) the client is between the ages of 13 and 17 years old, and:
  - (a) has a substance use disorder or a mental or behavioral disorder due to psychoactive substance use and is not intoxicated and is not currently at risk of experiencing withdrawal symptoms;
  - (b) is not currently experiencing acute symptoms of physical or mental illness, and does not pose a risk to self or others;
  - (c) meets patient placement criteria defined by the American Society of Addiction Medicine for Clinically Managed Residential Treatment for adolescents;
  - (d) does not require intensive therapeutic intervention for serious mental illness as a primary diagnosis or severe emotional disturbance and/or aggressive behavior; and
  - (e) does not require 24-hour a day nursing care.
- (2) the client's parent(s) consents to treatment, or a court of competent jurisdiction has ruled that such consent is not required; and
- (3) the client consents to treatment.

(B) Developmentally Appropriate Services: The licensee shall ensure that treatment plans, facility programs and materials are tailored to adolescents. Program services shall address adolescent concerns, including education, community, juvenile justice, mental and physical health.

(C) Assessment: In addition to the requirements of 105 CMR 164.072, the licensee shall assess the following:

- (1) the client's educational status and remedial educational needs; and
- (2) the client's mental health status to determine whether a co-occurring mental health disorder is present.

(D) Medical Examination: A medical and health history and physical exam shall be conducted within 2 weeks of admission, unless documentation of a physical examination, conducted within one year prior to admission, is provided. With client's consent, the medical examination shall include laboratory tests for sexually transmitted diseases and, for females, pregnancy. Refusal to consent to medical examinations shall be documented, and shall not be grounds for discharge.

(E) Treatment Plan: In addition to the requirements of 105 CMR 164.073, the licensee shall ensure that the treatment plan is reviewed at least every 30 days, and includes:

- (1) a statement of the client's educational needs;



- (2) educational services to be provided;
  - (3) planned length of stay.
- (F) **Family Involvement in Treatment:** The licensee shall ensure that services, including family therapy, are offered to parents and family members. The licensee shall inform parents of program policies and procedures, including:
- (1) names and telephone numbers of staff whom parents may contact;
  - (2) program rules; and
  - (3) criteria for discharge.
- (G) **Treatment Services:** In addition to the requirements of 105 CMR 164.074 Minimum Treatment Service Requirements, the licensee shall provide the following:
- (1) educational services designed to assist the client in maintaining or achieving participation in a developmentally appropriate school program;
  - (2) mental health services to address co-occurring mental health disorders;
  - (3) group programming for families of clients;
  - (4) recreational programming;
  - (5) exposure to support and self-help groups for adolescents;
  - (6) opportunities for clients to participate in planning, organizing or managing non-clinical programming;
  - (7) clinical, educational and support services designed specifically for females, separate from males, and for males, separate from females;
  - (8) clinical, educational and support services designed to incorporate and address issues related to cultural and ethnic identity of clients; and
  - (9) transportation services to ensure residents can obtain needed off-site services, such as medical, psychiatric and recreational services, and to support parent and family participation in program services and activities.
- (H) **Length of Stay:** If the client's length of stay exceeds 90 days, the licensee shall document reasons for this extension in the client's record.
- (I) **Aftercare Services:** The licensee shall ensure that the aftercare service plan provides for continued educational services, and continued family and social support services, including:
- (1) referrals for outpatient substance abuse treatment services;
  - (2) identification of self-help resources such as Alcoholics Anonymous (AA), Narcotics Anonymous (NA), Al-Anon, and Alateen;
  - (3) referrals for continued family therapy.

**164.443 Visits, Mail and Telephone**

The licensee shall establish policies and procedures to encourage and support family visits, mail, telephone calls, and other forms of communication with family, friends, or other persons. Such policies shall be distributed to staff and residents, and to parents prior to admission, when possible, or within 72 hours after admission.

**164.444 Staffing Pattern**

In addition to the requirements of 105 CMR 164.082 Special Populations, subsection (B), the licensee shall require that all staff are knowledgeable about adolescent development and adolescent substance abuse as well as co-occurring mental disorders. The licensee shall establish a staffing pattern in

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sufficient numbers and positions necessary for the level of care provided. Staffing pattern shall include the following positions:

- (A) a full-time equivalent Senior Clinician responsible for reviewing and approving mental health assessments conducted by Clinicians;
- (B) a Clinician;
- (C) at least one FTE staff on each shift;
- (D) no on-duty staff shall be permitted to sleep during their shift.

**164.450 RESIDENTIAL PROGRAMS FOR OPERATING UNDER THE INFLUENCE SECOND OFFENDERS**

**164.451 Scope**

Provisions of 105 CMR 164.452 through 164.453 apply to licensees providing residential programs for Operating Under the Influence Second Offenders. The licensee shall also comply with all provisions of 105 CMR 164.400 through 164.409, and with provisions of Part One of these regulations.

**164.452 Provision of Services:**

(A) Admission: The licensee shall admit clients who are referred by a Massachusetts court pursuant to the provisions of M.G.L. c. 90, §24.

- (1) Level of Care: At admission, the licensee shall determine that residential second offender services are appropriate based upon the court referral and the client's absence of withdrawal symptoms.
- (2) Denial of Admission: The licensee shall not admit an intoxicated individual. In the event of denial of admission due to intoxication, the licensee shall notify the referring court of the denial within one business day. The licensee shall provide a copy of the written notice to the individual who was denied admission.
- (3) Medical Assessment: Prior to admitting an individual, the licensee shall ensure that a medical evaluation is conducted by a qualified health care professional to establish whether the individual's health status is appropriate for the level of care provided by the program. The medical report shall determine:
  - (a) whether the individual suffers from acute or chronic medical conditions requiring immediate medical care; and
  - (b) whether the individual has any physical limitation which would limit participation in any program component, such as physical exercise. If such a condition exists, the licensee shall make, and document, efforts to adapt the physical requirements of the program to meet the individual's physical abilities.

If, as a result of the individual's medical or physical condition, the licensee is unable to provide adequate care, the licensee shall notify the referring court.

(B) Program Structure: The licensee shall establish a program structure that includes:

- (1) At least 14 consecutive days of residential programming;
- (2) Policy and procedures governing telephone, mail and visitation privileges;
- (3) A daily schedule of resident activities and rules governing resident participation in these activities;
- (4) Provisions for security that include:
  - (a) Measures to ensure that residents do not leave the facility without notifying a member of the administrative or counseling staff;
  - (b) A sign-in and sign-out system for all visitors, staff and residents; and,
  - (c) A census count to be taken once during each 8-hour shift.

**(C) Services: The licensee shall provide the following:**

- (1) Three individual counseling sessions for each resident during the 14-day stay, including an initial evaluation session, a termination session, and one intermediate session.**
  - (2) Educational and motivational groups, as follows:**
    - (a) Two 1.5 hour groups each day. Over any two week period, at least 14 of such groups shall be educational and at least 10 shall be motivational.**
    - (b) A written educational curriculum, approved by the Department, which:**
      - (i) addresses the physiological, psychological and social consequences of substance abuse;**
      - (ii) assists residents to identify their substance abuse behavior, recovery methods and treatment options;**
      - (iii) teaches techniques for changing problematic behavior resulting from or contributing to substance abuse.**
    - (c) Community or self-help group meetings shall not be substituted for required educational and motivational groups.**
  - (3) A physical education program consisting of planned, regularly scheduled activities, monitored by a staff member who is certified in CPR.**
- (D) Discharge: The licensee shall discharge residents upon completion of their sentence and shall refer residents who continue on probation for additional substance abuse treatment. With the client's written consent, the licensee shall provide the outpatient provider with a summary of the client's completed assessment and diagnosis.**
- (E) Aftercare: If a resident completes the probation period at the same time as the residential program, the licensee shall provide referrals to ensure a continuum of care for the resident, including referrals for further substance abuse treatment, the provision of post discharge counseling and other supportive services.**

**164.453 Notice to the Court**

The licensee shall establish procedures for notifying court personnel when the program is operating at capacity and cannot accept additional referrals, and when it is available for additional referrals.

**164.454 Staffing Pattern**

The licensee shall establish a staffing pattern with sufficient personnel to oversee daily activities and to ensure safe operation of the program, which shall include:

- (A) A Senior Clinician or Clinician to provide individual counseling, and group counseling/education services.**
- (B) Staff qualified by education or experience responsible for the structure and delivery of physical education and recreation activities.**
- (C) Qualified health care personnel to conduct initial medical assessments. Health care staff may be employees of the licensee, or may be employees of an entity with whom the licensee has a Qualified Service Organization Agreement for provision of health care services.**
- (D) No on duty staff on any shifts shall be permitted to sleep during the shift.**

**105 CMR 164.000 M.G.L. c. 111, § 3; c. 111B, c. 111E; and c. 90, §§ 24, 24D and 24P**

**Appendix A**

164.001

164.002

164.006

164.007

164.008 (A), (B)

164.010 (A)(1), (3), (6), (7), (8); (B)

164.011

164.012 (A), (B), (C), (D) (2), (E), (F), (G), (H)

164.013

164.014

164.015

164.016

164.017

164.018

164.019

164.020

164.021

164.023

164.031

164.034

164.040 (A)(20)

164.044 (B)(2)(b), (d), (e), (f); (D); (F)

164.047 (A), (B) (2)

164.048 (B) (1), (D)

164.070 (C), (G), (H), (I)

164.072

**164.073 (A)**

**164.074 (A), (B), (D), (I), (J)**

**164.075 A(3)(h)**

**164.076**

**164.079 (B) (16)**

**164.082 (A), (B), (C)**

**164.083 (B)(5)**

**164.084**

**164.132**

**164.133(A)(1)(a)(1), (2)(i); (A)(2); (B)(1)(a), (b), (d); (B)(2), (3); (C); (D)**

**164.133 (C)** The program specified in **164.012 (D)(2)(b)** is required to comply with **164.300** provisions identified in Appendix A below.

**164.134 (A); (B) (5)**

**164.211 thru 164.234**

**164.302 (A)(2), (A) 3)(b) and (c), (A)(4) (a), (e), (h); (D)(1); (E) (1), (2), (3)**

**164.303 (A)(2); (B)(1), (2), (4)**

**164.304 (B)(4); (G)**

**164.305**

**164.311**

**164.312 (B)**

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**Appendix B**

164.001

164.002

164.006

164.007

164.008

164.010 (A)(1), (3), (6), (7), (8); (B)

164.011

164.012 (A), (B), (C), (D)(3) (4), (E), (F), (G), (H)

164.013

164.014

164.015

164.016

164.017

164.018

164.019

164.020

164.021

164.023

164.031

164.034

164.040 (A)(20)

164.044 (B)(2)(b), (d), (e), (f); (D); (F)

164.047 (A), (B)(2)

164.048 (D)

164.070 (G), (H), (I)

164.072 (A), (B), (C), (D), (E), (F), (H)

**164.073 (A)**

**164.074 (A), (B), (D), (I), (J)**

**164.079 (B) (16)**

**164.082 (A) and (B)**

**164.083 (B)(5)**

**164.084**

**164.132**

**164.133(A)(1)(b)(1), (2)(i); (A)(2); (B)(1)(a), (b), (d); (B)(2), (3); (C); (D)**

**164.133 (C)** The program specified in **164.012 (D)(3)(b)** is required to comply with **164.300** provisions identified in Appendix B below.

**164.134 (A); (B) (5)**

**164.302 (A)(2), (A) 3)(b) and (c), (A)(4) (a), (e), (h); (D)(1); (E) (1), (2), (3)**

**164.303 (A)(2); (B)(1), (2), (4)**

**164.304 (B)(4); (G)**

**164.305**

**164.311**

**164.312 (B)**